84-1217

No. ——

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ALEXANDER L. STEVAS,
CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1984

STERLING DRUG INC.,
Petitioner,

v.

FEDERAL TRADE COMMISSION,
Respondent.

PETITION (WITH APPENDIX) FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

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QUESTIONS PRESENTED

1. Whether the court of appeals erred in affirming the Federal Trade Commission's broad multi-product order on the basis of its own purported findings of wrongful intent, willfulness, and repeated wrongdoing by the petitioner, Sterling, when the agency had made no such findings.

2. Whether the court of appeals' affirmance of the Federal Trade Commission's refusal to consider Sterling's scientific substantiation for its Bayer Aspirin advertising was erroneous as a matter of law because (a) inconsistent with the First Amendment's protection of commercial speech in areas of scientific controversy, and (b) inconsistent with the "reasonable basis" standard applicable under the Federal Trade Commission Act.

3. Whether the court of appeals erred in failing to apply the proper standard of review by not examining the whole record, and by not correcting the Federal Trade Commission's failure to take account of crucial evidence.

4. Whether the court of appeals erred in failing to set aside the Federal Trade Commission's decision and order on the ground that it arbitrarily imposed the same broad relief against Sterling as against its competitors in two companion cases, notwithstanding sharp differences in the records.

PARTIES TO THE PROCEEDING

Sterling Drug Inc. and two of its former advertising agencies were named in the administrative complaint of the Federal Trade Commission (FTC or Commission). Sterling was the only respondent party to the FTC proceeding through its completion. Sterling alone sought review of the FTC's order in the court of appeals and it is the only party petitioning this Court.

Pursuant to Supreme Court Rule 28.1, Sterling states that it has no parent companies, and no partially-owned domestic subsidiaries or affiliates. The following is a list of partially-owned foreign subsidiaries:

P. T. Sterling Products, Indonesia

Quimica Farmaceutica Platense, Argentina

Sterling Products (Nigeria Ltd.)

Sterling Products (Ghana Ltd.)

Mackwoods-Winthrop, Ltd.—Sri Lanka

Dainichiseika-Sterling Co. Ltd.—Japan

Inrock Chemical Co. Ltd.—Japan

Sterling Products (Pakistan) Ltd.

Sterling Drug (Korea) Ltd.

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FEDERAL TRADE COMMISSION,
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PETITION FOR WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

Petitioner Sterling Drug Inc. ("Sterling") hereby petitions for issuance of a writ of certiorari to review the judgment of the United States Court of Appeals for the Ninth Circuit which affirmed and enforced an order issued by the respondent Federal Trade Commission.

OPINIONS BELOW

The Ninth Circuit's opinion, set forth in the Appendix at 1a, is reported at 741 F.2d 1146. The Opinion

and Order of the FTC, set forth in the Appendix at 32a, is reported at 102 F.T.C. 395, 744.

JURISDICTION

The judgment of the court of appeals was entered on August 28, 1984 and a timely petition for rehearing was denied on October 29, 1984. The Court has jurisdiction under 28 U.S.C. § 1254(1).

CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

The constitutional provisions involved are the First and Fifth Amendments to the United States Constitution, which provide, respectively, in pertinent part:

> "Congress shall make no law . . . abridging the freedom of speech . . . ."

and

> "No person shall be . . . deprived of . . . property, without due process of law . . . ."

The statutory provision involved is Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45, which provides, in pertinent part:

> "(a)(1) Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful."
>
> . . .
>
> "(c) . . . The findings of the Commission as to the facts, if supported by evidence, shall be conclusive."

STATEMENT OF THE CASE

This proceeding was commenced by the Federal Trade Commission's issuance of a complaint in 1973 charging Sterling and two advertising agencies[1] with violations of Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52, in advertising for six nonprescription internal analgesic products: Bayer Aspirin, Bayer Children's Aspirin, Vanquish, Cope and Midol. On the same day, complaints were issued against two of Sterling's competitors in the analgesic field.[2]

The Commission ruled for Sterling on a substantial number of issues. Among others, it dismissed all of the charges against Bayer Children's Aspirin and Vanquish (Pet. App. 51a-53a, 56a-58a); and it sustained petitioner's defense of its principal advertising claim during the period at issue—namely, that Bayer Aspirin was superior in overall pharmaceutical quality to all other 5-grain aspirin tablets as shown by a large-scale pharmaceutical study (Pet. App. 80a-82a, 110a-111a).[3]

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[1] The two advertising agencies were no longer parties to the case during its administrative phase (Pet. App. 35a).

[2] These were Bristol-Myers Co., maker of Excedrin and Bufferin, and American Home Products Corp., maker of Anacin and Arthritis Pain Formula. The FTC's decision in *Bristol-Myers* was rendered on the same day as the decision in this case, 102 F.T.C. 317 (1983), *aff'd*, 738 F.2d 554 (2d Cir. 1984), *cert. denied*, —— U.S. —— (Jan. 21, 1985). The FTC had earlier decided *American Home*, 98 F.T.C. 136, 362-427 (1981), enforced as modified, 695 F.2d 681 (3d Cir. 1982), modified by the FTC to conform to the *Bristol-Myers order*, —— F.T.C. —— (February 7, 1984), *modified*, —— F.T.C. —— (April 11, 1984).

[3] The issues on which Sterling was sustained were as follows:

As for the violations found, the Commission held that some Bayer advertising making *pharmaceutical quality* claims in the early 1970's had impliedly represented that Bayer was *therapeutically* superior to any other aspirin and such therapeutic superiority had been scientifically established (Pet. App. 41a-49a); and that these claims of established therapeutic superiority were not substantiated. In so holding, the FTC refused to consider a large body of substantiating scientific evidence on the ground that only clinical tests were acceptable. (Pet. App. 62a-72a). As a result, the Commission refused to accept the testimony of recognized scientific experts that therapeutic comparisons among different brands of 5-grain aspirin tablets could be reliably based upon nonclinical chemical and pharmacological evidence. It also found violations with regard

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(a) Bayer Aspirin's claim of pharmaceutical superiority to all other 5-grain aspirin tablets (Pet. App. 81a-82a, 110a-111a);

(b) alleged Bayer Children's Aspirin claim of therapeutic superiority and established therapeutic superiority to other children's aspirin (Pet. App. 51a-53a);

(c) alleged Vanquish claims of therapeutic superiority and established therapeutic superiority in effectiveness and freedom from side effects to other non-prescription internal analgesics, and alleged Vanquish misrepresentation of aspirin ingredient (Pet. App. 56a-58a, 82a-83a, 94a);

(d) alleged Cope claim of superior effectiveness for nervous tension headache and alleged Cope misrepresentation of aspirin ingredient (Pet. App. 82a-83a, 94a);

(e) alleged Midol misrepresentation of caffeine ingredient (Pet. App. 99a); and

(f) allegation of mutually inconsistent claims (Pet. App. 100a-104a).

to a few Bayer statements claiming specific pharmaceutical attributes,[4] and as to certain ingredient and relief representations in a number of ads for Cope and Midol.[5]

The FTC entered a broad, multi-product order against Sterling which reached: products as to which alleged violations were rejected; all of Sterling's nonprescription internal analgesics; and, in one section, all of Sterling's nonprescription drug products. The order's principal terms are the same as those imposed in the companion cases against Sterling's competitors who were found to have made misleading claims for more than 15 to 25 years, including explicit claims of therapeutic superiority and misrepresentation of ingredients.

The FTC order (Pet. App. 121a-126a) requires Sterling to have two or more "adequate well-controlled clinical investigations" to support any claim that superior effectiveness has been established for Bayer

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[4] The Commission found that five Bayer ads represented superiority with respect to purity, freshness, stability and speed of disintegration and that despite Bayer's overall pharmaceutical superiority, its superiority in these four specific respects was not substantiated (Pet. App. 50a, 76a-81a).

[5] The FTC found that two Cope ads improperly represented that it had a "unique formula" (Pet. App. 99a-100a) and that four Midol ads improperly created the impression that its analgesic ingredient was something other than aspirin (Op. 46-48). It found that three ads had represented that Cope was established to be superior to other analgesics for relief of nervous tension headaches (Pet. App. 58a-60a) and that this superiority was not substantiated (Pet. App. 74a-76a). Finally, it found that Cope and Midol advertising had made unsubstantiated claims for tension or mood relief (Pet. App. 84a-94a).

Aspirin, Bayer Children's Aspirin, Vanquish, Cope, Midol or any other nonprescription internal analgesic (Pet. App. 121a-122a); and to have a "reasonable basis" for any other "therapeutic performance claim" for such products (Pet. App. 124a). The company is barred from making claims of superior freshness, purity, stability or speed of disintegration for such products without "competent and reliable scientific evidence" (Pet. App. 123a-124a); and it may not make claims for any nonprescription drug that the product contains any unusual, special or unique ingredient when such ingredient is commonly used in other nonprescription drugs intended for the same use (Pet. App. 125a). Sterling is barred from representing that the analgesic ingredient in any aspirin-containing nonprescription internal analgesic is different from aspirin or from otherwise misrepresenting the identity of any analgesic ingredient, and it is required to disclose the aspirin ingredient in certain comparative ads (Pet. App. 125a-126a).

The court of appeals affirmed the FTC in all respects (Pet. App. 2a, 25a). On the findings of violations, the court mainly stressed that it would not "reweigh" the evidence (Pet. App. 10a-14a). On the scope of relief, the Court stressed the ostensibly "deliberate" nature of the violations, Sterling's supposed "intent" to mislead and its "pattern" of transferring false claims from one product to another (Pet. App. 19a-23a). None of these purported findings had been made by the Commission.

BASIS FOR FEDERAL JURISDICTION IN THE COURT OF FIRST INSTANCE

Pursuant to Section 5(c) of the Federal Trade Commission Act, 15 U.S.C. § 45(c), the United States Court of Appeals for the Ninth Circuit had jurisdiction to review Sterling's appeal from the FTC's order.

REASONS FOR GRANTING THE WRIT

This case presents important questions concerning the standard to be applied by courts of appeal in reviewing decisions of administrative agencies, and regarding FTC regulation of advertising, including the application of the First Amendment to "commercial speech." We submit that the Ninth Circuit, by its uncritical affirmance of the broad, multi-product order in this case, flouted basic rules governing relations between court and agency as laid down in *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947) and *Universal Camera Corp.* v. *NLRB*, 340 U.S. 474 (1951). Its (and the Commission's) rejection of Sterling's proffered substantiation in an area of genuine scientific controversy violates the First Amendment and the Federal Trade Commission Act and is contrary to the position on advertising regulation adopted by another court of appeals.[6] Because of the serious errors in the decision

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[6] *FTC* v. *National Commission on Egg Nutrition*, 517 F.2d 485 (7th Cir. 1975), *cert. denied*, 426 U.S. 919 (1976); *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 157 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978). No similar issues regarding First Amendment limitations on advertising regulation in areas of genuine scientific controversy were presented by the petition for certiorari in *Bristol-Myers*, n. 2, *supra*, which this Court denied on January 21, 1985. For discussion of other distinctions between this case and *Bristol-Myers*, see *infra*, pp. 22-23.

below, the importance of the questions raised under the First Amendment and the FTC Act, the conflict with the decision of another court of appeals, and the necessity to maintain a proper judicial check on arbitrary agency action, plenary review by this Court is warranted.

I. The Court Below Violated The Chenery Rule In Sustaining The FTC Order On Grounds Not Found By The Agency

The decision below violated the "fundamental rule of administrative law" enunciated by this Court in *SEC* v. *Chenery Corp.*, 332 U.S. 194 (1947), that a reviewing court must judge the propriety of agency action "solely by the grounds invoked by the agency. If those grounds are inadequate or improper, the court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." 332 U.S. at 196-97. This Court has repeatedly reversed courts of appeal which failed to observe this principle. *See, e.g. Vermont Yankee Nuclear Power Corp.* v. *Natural Resources Defense Council,* 435 U.S. 519, 549 (1978); *Burlington Truck Lines, Inc.* v. *U.S.,* 371 U.S. 156, 168-69 (1962).

The Ninth Circuit transgressed the *Chenery* rule when it upheld the broad scope of relief ordered by the Commission in this case on the basis of the court's own "findings" as to Sterling's supposed wrongful intent, willfulness and recidivism. Such "findings" were plainly intended to bring this case within prior decisions of this Court, and of other panels of the court below, that had upheld broad multi-product FTC orders on the basis of "deliberate" conduct in "utter disregard of the law" (*FTC* v. *National Lead Co.,* 352 U.S. 419, 429 (1957); *Sears, Roebuck & Co.* v. *FTC,*

676 F.2d 385, 392, 394 (9th Cir. 1982); *Litton Industries Co.* v. *FTC*, 676 F.2d 364, 370-71 (9th Cir. 1982); *see* Pet. App. 17a-18a). The decision below is untenable because the FTC here made *no such findings* of deliberateness or repeated wrongdoing.

This error applies particularly to the two provisions of the FTC order dealing with substantiation of therapeutic performance claims. Thus, the court below upheld the provision requiring rigorous clinical studies to support claims of established therapeutic superiority for all of Sterling's nonprescription internal analgesic products by finding that Sterling's violations in this regard for Bayer Aspirin and Cope had been "deliberate," and that the ads had incorporated features "intended to subtly persuade consumers," and were "so intentionally subtle" as to dupe consumers (Pet. App. 18a-19a).

In fact, no such findings were made by the FTC. It found that Sterling had made the alleged claims of therapeutic superiority for Bayer and Cope (Pet. App. 41a-49a, 58a-60a), but it did not find any improper intent and did not even raise or consider that question. Indeed, with respect to the principal product at issue, Bayer Aspirin, the FTC characterized the alleged therapeutic performance claims as "implied," and they were found to have been made only because they "could reasonably be considered" or "assumed" to have been communicated (Pet. App. 42a-46a). That fact, together with the large body of substantiating evidence (*infra,* pp. 12-13), clearly precluded any finding of improper intent. In any event, under *Chenery,* it is conclusive that the Commission, itself, did not make any such finding, and the court's affirmance of the agency order on that basis was erroneous.

The same error invalidates the court of appeal's affirmance of the Commission's requirement of a "reasonable basis" for all therapeutic claims for all of petitioner's nonprescription analgesics. In this regard, the court's opinion referred to therapeutic efficacy claims for Cope, Vanquish, Midol and Bayer, and then "found" that Sterling had a "pattern of transferring this deceptive practice from one product to another . . ." (Pet. App. 22a). Once again, the Commission made no such finding.

The *only* violations found by the FTC on a reasonable basis theory related to claims for nervous tension relief for Cope and Midol (Pet. App. 84a-85a, 112a).[7] While the FTC expressed the opinion that this kind of violation "can easily be transferred to other sorts of claims" (Pet. App. 111a-112a), it *did not find* that Sterling had ever done so or shown any propensity to do so. This left a serious gap, since broad relief raises the question, not whether transfer is *possible* in the abstract, but whether there is a significant risk that a particular respondent will engage in such improper conduct—i.e., whether there is a "likelihood of the petitioner committing the sort of unfair practices they prohibit" (*Litton Industries* v. *FTC*, 676 F.2d at 370-71; *see Sears, Roebuck & Co.* v. *FTC*, 676 F.2d at 392).[8] The court's attempt to fill that gap with its own finding was contrary to *Chenery* and erroneous.

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[7] The opinion below stated that the Commission found "no reasonable basis" for a claim of Vanquish's therapeutic superiority (Pet. App. 5a). To the contrary, the Commission dismissed such allegations on the ground that the complaint's theory of liability was untenable (Pet. App. 82a-83a). There were no findings of any violations for Vanquish. (*See* n. 3, *supra*).

[8] The only mention anywhere in the FTC's opinion of whether

Similarly, the court of appeals upheld multi-product relief covering four pharmaceutical characteristics on the ground that the violation found by the FTC "was deliberate" (Pet. App. 20a). But, again, the Commission did not even consider the issue of deliberateness, and it made no such finding.

On these issues of Sterling's wrongful intent and "pattern" of transgression, the court of appeals may have been led into error by the FTC's brief below which charged Sterling with "serious," "deliberate" and "blatant" misconduct, and a "propensity," "demonstrated tendency" and "inclination" to violate the law.[9] It is, of course, well-settled that "appellate coun-

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Sterling's violations were intentional concerned several advertisements that a formula for Cope was unique, relevant to a provision of the agency order other than those discussed above. The Commission stated that "it appears Sterling knew its Cope ads were false" because it was "aware" that such ingredients were used in another product, Excedrin PM, introduced four years after Cope (Pet. App. 99a-100a, 114a). However, the FTC did *not* find that the claim was a "deliberate" violation, as contended by the court below (Pet. App. 23a). One reason may have been that the claim was undeniably proper during most of the period when made, before Excedrin PM was introduced. Moreover, it was uncontroverted that the products differed in their formulas and in their intended (and advertised) uses. Excedrin PM had a strictly limited and specialized use as a night-time remedy, to induce sleep, and could not have been used, like Cope, against regular nervous tension headaches (RX 246; Tr. 8160-67, 154-75, 1551). For that reason, it is doubtful that the challenged Cope ads would even violate the FTC's order under review, which prohibits advertisement of product uniqueness *only* when other products with common ingredients are "intended for the same use or uses" (Pet. App. 125a). It should be noted that Cope advertising ceased in 1971 and the formulation at issue is no longer on the market (Pet. App. 99a).

[9] Brief for Respondent Federal Trade Commission in the court below, pp. 36, 44, 47.

sel's *post hoc* rationalizations for agency action" cannot be substituted for agency findings based on substantial evidence. *Burlington Truck Lines, Inc.* v. *U.S.*, 371 U.S. at 168-69. The absence of any FTC findings on these points calls for reversal of the judgment below—not merely to redress the court's error but to make it plain that the *Chenery* rule must be observed.

II. The Rejection Of Sterling's Scientific Substantiation In An Area Of Genuine Scientific Controversy Was Inconsistent With Both The First Amendment's Protection Of Commercial Speech And The FTC Act's Reasonable Basis Standard

The court below committed legal error in an area of substantial significance to FTC regulation of advertising when it upheld the agency's refusal to consider and evaluate the large body of scientific data and expert testimony comparing Bayer Aspirin with other 5-grain aspirin tablets that Sterling presented in substantiation of its alleged therapeutic performance claims. The court's error raises important questions regarding application of the First Amendment and the FTC Act, warranting review by this Court.

The key scientific issue at trial with respect to Bayer Aspirin was whether scientific evidence other than clinical tests could be used in making therapeutic performance comparisons among different brands of 5-grain aspirin tablets. Petitioner presented highly-reputed scientists, including a renowned expert in clinical testing from the Yale Medical School, who testified unequivocally that in considering different brands of the same drug and dosage form, such as 5-grain aspirins, it is possible to compare directly "physicochemical properties" and "pharmacokinetic inform-

ation." Hence, unlike the situation presented by different drugs and dosage forms, such data can be used as a "basis for comparison" among brands of 5-grain tablets, and for making a judgment of superiority in "therapeutic action" (*e.g.*, Tr. 16239, 16369, 16488-89, 16492, 16496-97).[10]

The court of appeals summarily dismissed this aspect of Sterling's appeal on the ground that it "cannot reweigh the evidence" and that the Commission was entitled to make its own "resolution of the evidentiary conflict" among the scientific witnesses, even though there was scientific "evidence support[ing] Sterling's position" (Pet. App. 13a-14a). This ruling is inconsistent with the First Amendment and the FTC Act.

1. *First Amendment.* It is now well settled that the First Amendment protects "commercial speech," such as product advertising.[11] While this Court has left room for regulation of "false . . . deceptive or misleading advertising,"[12] the FTC does not have free reign. Regulatory action must meet the burden of justification imposed upon any restriction on commer-

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[10] Testimony to this effect was presented by experts in clinical testing, in medicine, pharmacology and pharmaceutics, as summed up in our briefs to the court below, Brief of Petitioner Sterling Drug Inc. at pp. 18-19, 22-23, Reply Brief at pp. 9-11. *See* the Administrative Law Judge's Findings 1154, 1156-1161; Pet. App. 136a-138a.

[11] *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. 748 (1976); *Bates* v. *State Bar of Arizona*, 433 U.S. 350 (1977); *Bolger* v. *Young's Drug Products Corp.*, 103 S.Ct. 2875 (1983).

[12] *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. at 771-72; *Bates* v. *State Bar of Arizona*, 433 U.S. at 383; *Bolger* v. *Young's Drug Products Corp.*, 103 S.Ct. at 2881.

cial speech[13] and must not obstruct the proper role of advertising in the "marketplace of ideas."[14] We submit that the First Amendment, at a minimum, guarantees advertisers the right to present their side in scientific controversies where there is room for legitimate differences of opinion.

This First Amendment right is inherent in the constitutional protection of commercial speech. It was recognized by another court of appeals, the Seventh Circuit, when it reviewed an FTC order in another area of scientific controversy—the relationship between cholesterol consumption and heart disease.[15] The court there pointed out that serious First Amendment questions would be raised if the agency were to prohibit advertising which "espoused one side of a genuine controversy".[16] Accordingly, it set aside a pro-

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[13] *Bolger* v. *Young's Drug Products Corp.*, 103 S.Ct. at 2882; *Linmark Associates, Inc.* v. *Willingboro*, 431 U.S. 85, 95 (1977); *In Re R.M.J.*, 455 U.S. 191, 203 (1982); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. at 760.

[14] *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council*, 425 U.S. at 760.

[15] *FTC* v. *National Commission on Egg Nutrition*, 517 F.2d 485, 489-90 (7th Cir. 1975), *cert. denied*, 426 U.S. 919 (1976); *National Commission on Egg Nutrition* v. *FTC*, 570 F.2d 517 (7th Cir. 1977), *cert. denied*, 439 U.S. 821 (1978).

[16] 517 F.2d at 489, 490. Chief Judge Fairchild went further and stated that in an area of "genuine controversy," the FTC's "mere reason to believe that a statement is false or misleading" should not be "a sufficient basis for an injunction. The First Amendment at least requires a higher standard." (517 F.2d at 490). The parties in that case were found in violation because they represented that there was no scientific evidence on the other side of the controversy (517 F.2d at 489; 570 F.2d at 160-61, 163).

vision of an FTC order which, in its view, interfered unnecessarily with the advertiser's "effective presentation" of its position in that area of scientific dispute (570 F.2d at 164).[17]

There can be no doubt that here there is at the least a "genuine controversy" about the use of nonclinical data as a basis for making therapeutic comparisons among 5-grain aspirin tablets. This is clear from the testimony of petitioner's expert witnesses, and their high professional standing. Indeed, the court below did not find otherwise, since it explicitly acknowledged the existence of an "evidentiary conflict." (Pet. App. 14a). Nevertheless, the court approved the Commission's erroneous assertion of the power to choose among scientific experts, to resolve "the evidentiary conflict" against Sterling, and to enter an order on that basis (Pet. App. 14a). This result unconstitutionally impinges upon a protected category of speech (*Bose Corp.* v. *Consumers Union of United States, Inc.*, 104 S.Ct. 1949, 1961, and n.22 *reh. denied*, 104 S.Ct. 3561 (1984); *Central Hudson Gas and Electric Corp.* v. *Public Service Commission*, 447 U.S. 557, 562 (1980)), and is precluded by the First Amendment.

Finally, review by this Court is required to eliminate the conflict and confusion in the courts of appeals regarding the legal standard to be applied by the Com-

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[17] The Seventh Circuit set aside an order provision requiring a statement in future ads that many experts took a position contrary to that of the advertisers. Such disclosure was limited by the court to ads in which the advertisers themselves made representations as to the state of available evidence; the advertisers were then to disclose that "there is a controversy among medical experts" and that [they were] "presenting their side of that controversy." (570 F.2d at 164, 166).

mission and the courts in determining whether commercial speech is deceptive and, therefore, not entitled to First Amendment protection. Although this Court has focused on the standards required by the First Amendment in other contexts,[18] it has not yet provided similar guidance with respect to claims of deception in advertising and other commercial speech.

2. *FTC Act.* The court of appeals' decision not only raises serious First Amendment issues, but it is also inconsistent with the Commission's own test for the validity of advertising under the FTC Act. As enunciated in *Pfizer, Inc.*, 81 F.T.C. 23 (1972), that test is whether the person making the representation had a reasonable basis for the claim at the time it was made.[19]

The "reasonable basis" standard has particular implications for a claim in an area of scientific controversy for it is inherent in such controversy that both sides will have substantial support.[20] In that context,

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[18] *E.g., New York Times Co.* v. *Sullivan*, 376 U.S. 254 (1964), and its progeny, which address and articulate the legal standards that govern causes of action for libel so that such actions do not unduly impede the exercise of First Amendment rights. The need for intelligible rules governing the interplay of the First Amendment and the regulation of deceptive advertising is underscored by the lower court's assumption in this case that the Commission was free to adopt and impose its view of the "truth," even in an area of genuine scientific controversy.

[19] The "reasonable basis" test was recently reaffirmed in FTC Policy Statement Regarding Advertising Substantiation, 49 Fed. Reg. 30999 (1984).

[20] This was recognized by the FTC in the present case, when it rejected a charge that making inconsistent claims was *ipso facto* a violation of the Act. It pointed out that "two inconsistent claims could both be substantiated with a reasonable basis" and held, accordingly, that the charge was "contrary to principles of law set forth in *Pfizer* and its progeny." (Pet. App. 101a-103a).

it is not the Commission's proper role under the "reasonable basis" test "to determine . . . whose interpretation of a difficult and incomplete body of scientific literature is superior." *National Commission on Egg Nutrition,* 88 F.T.C. 89, 182 (1976), *modified,* 570 F.2d 157 (7th Cir. 1977), *cert. denied,* 439 U.S. 821 (1978).[21]

The decision below flouted the FTC Act as interpreted "in *Pfizer* and its progeny" when it upheld the Commission's decision on Bayer substantiation. It was not the FTC's proper role to arrive at a "resolution" of the "evidentiary conflict" among the scientific experts in this case, as the court of appeals allowed (Pet. App. 13a-14a).[22] The issue was whether Sterling

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[21] *See also* the statements in *Pfizer, Inc.*, 81 F.T.C. at 70, that a "possible conflict" among experts "does not satisfy the burden of proof resting upon complaint counsel;" and in *Crown Central Petroleum Corp.*, 84 F.T.C. 1493, 1544 (1974), *amended after remand,* 88 F.T.C. 210 (1976), that "it was not advisable or helpful to try to draw a non-disputable conclusion from the disparate views" of experts.

[22] Note the lower court's careful statements that "the Commission agreed with the ALJ's resolution of the evidentiary conflict," and that the ALJ had not "ignored" Sterling's evidence, rather than that the Commission had resolved the conflict. In fact, the Administrative Law Judge gave full credit to petitioner's experts (see his Findings 1154, 1156-1161; Pet. App. 136a-138a) and then stated a conclusion based upon the opposing testimony, which was in blatent conflict with the "reasonable basis" standard. Perhaps because of this gross legal error, the Commission took a different tack, in essence refusing to admit the existence of the distinguished expert testimony in favor of petitioner's position. *See* Pet. App. 62a-68a; *see* n. 10, *supra.* The FTC thus cited an alleged "consensus of experts" against Sterling (Pet. App. 62a-63a, 65a-66a, 72a). To the extent this was an assertion that no significant expert opinion supported petitioner, it was not accepted by the Administrative Law Judge or the court below, and it was clearly wrong on

had a reasonable basis for the alleged claims of Bayer's therapeutic superiority over other 5-grain aspirins. If there was such a basis in the form of support by reputable scientific opinion, as there was, no violation of the FTC Act could be found. It was irrelevant that the FTC staff was able to find experts who took a different view. The decision below erred as a matter of law in sustaining the Commission's ruling; and that error is particularly grievous, and warranting review by this Court, because of the important First Amendment implications we have noted above.

III. The Court Below Erred In Failing To Evaluate The FTC's Decision And Order On The Record As A Whole And In Failing To Reverse The Agency For Not Taking Account Of Crucial Evidence.

In reviewing the FTC's decision, the court of appeals was obliged to examine it against the "whole record"; "the substantiality of evidence must take into account whatever in the record fairly detracts from its weight." *Universal Camera Corp.* v. *NLRB,* 340 U.S. 474, 487-88 (1951). Like the *Chenery* rule discussed in Point I, this is a fundamental requirement of proper judicial review of administrative decisions and a check on arbitrary action.

We submit that the court of appeals failed to apply the *Universal Camera* rule in this case. It was satisfied

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the record. Indeed, the Yale Medical School expert testified that "a great many" or "most" people in the field would favor the use of nonclinical data in these circumstances, and that this was the consensus of colleagues with whom he discussed the case (Tr. 16492-93; *see also,* Petitioner Sterling's Petition for Rehearing to the Ninth Circuit, pp. 9-10).

with generalized statements that the court could not re-weigh evidence (*e.g.*, Pet. App. 9a, 14a), or that the FTC did not ignore the evidence (*e.g.*, Pet. App. 10a-12a). It made no serious analysis of the substantiality of the evidence on the record as a whole to support the Commission's results, and took no account of the agency's failure to consider crucial evidence. *See Cinderella Career and Finishing Schools* v. *FTC*, 425 F.2d 583 (D.C. Cir. 1970).

A few examples will suffice to show the lack of substantial evidence to support the FTC's findings, and the unacceptable superficiality of the Ninth Circuit's review:

First, as we have shown above in Point II, such error was clearly made in the court's ruling that Sterling lacked substantiation for its alleged claims of Bayer's therapeutic superiority. Apart from the court's legal errors under the FTC Act and the First Amendment, it also failed to assess the FTC's conclusion against the large body of expert testimony affirming the use of nonclinical scientific evidence for the special purpose of comparing different brands of 5-grain aspirin.

Second, such error was made by the court in sustaining the FTC's finding that Bayer advertising made claims of therapeutic superiority. The opinion stated that the Commission had "assumed" that consumers would understand a "quality" claim to mean "a promise of therapeutic superiority" (Pet. App. 9a-10a). But such an "assumption" did not constitute substantial evidence. Nor do the court of appeals' "assumptions" as to the evidence fare any better. The opinion below failed to acknowledge that, with regard to about one-half of the ads involved, the ALJ specifically

found that no therapeutic performance claims were made (Findings 314, 316-17; Pet. App. 135a-136a); and it failed entirely to consider the FTC's assumption and conclusion in light of a copy test conducted by the agency itself which showed that no therapeutic claim was communicated to consumers.[23] This is a crucial part of the "whole record" on the basis of which the agency's decision should have been evaluated.

Third, in an effort to support broad multi-product relief, the Commission cited a "previous history of dealings with the F.T.C." by Sterling and found that this was "the second time" a cease-and-desist order had been entered against the company "regarding the advertising of its OTC analgesics." (Pet. App. 108a, 113a). The court of appeals uncritically accepted the FTC's reliance upon Sterling's supposed "past history of violations" (Pet. App. 19a).

In fact, there was *no* "past history" that would support the Commission's sweeping order. There is one 34-year-old order against Bayer advertising, but that ancient order had nothing whatsoever to do with product quality or therapeutic performance ads.[24] In

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[23] See the expert testimony and analysis of the copy test data, Amstutz Tr. 10019-22, 10040-46, 10051-52, 10061-63; Lipstein, Tr. 11987-90, 11992-93; RX 141(b) F, G, J, R, X. The court below professed to be satisfied by the fact that the copy test was not "ignored" by he FTC, since the agency gave reasons for not considering it (Pet. App. 11a-12a). In fact, the FTC's reasons were untenable (*see* Reply Brief of Petitioner Sterling Drug Inc. in the court below at 7-8), yet they were nowhere critically examined in the court's opinion.

[24] Brief for Respondent Sterling Drug Inc. in the court below at 38-39, Reply Brief at 3. *See Sterling Drug Inc.*, 47 F.T.C. 203, 205, 210 (1950) (price reduction, program sponsorship).

a further effort to depict Sterling as a repeated offender, the Commission (Pet. App. 108a-109a) and the court below (Pet. App. 19a) cited four consent decrees, all of which involved nonanalgesic products. Justifying the order on this basis was clear error since a consent settlement is no evidence of wrongdoing and cannot be relied upon for imposition of broad relief.[25] The court below erred in failing to correct the FTC on this alleged justification for broad relief.[26]

These points illustrate the lower court's failure to exercise the requisite critical scrutiny of the agency opinion on the whole record. The court's violation of the *Universal Camera* rule presents an additional reason for review by this Court.

IV. The Court Below Failed To Consider The FTC's Error In Imposing The Same Relief Against Sterling As In Cases Against Other Parties Despite Compelling Differences In This Record.

An issue before the court of appeals was the FTC's arbitrary insistence on imposing the same broad relief

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[25] *E.g., ITT Continental Baking Co.* v. *FTC*, 532 F.2d 207, 222-23 n.23 (2d Cir. 1976); *Beatrice Foods Co.*, 86 F.T.C. 1, 50 (1975), *modified*, 88 F.T.C. 1004 (1976); *see United States* v. *duPont & Co.*, 366 U.S. 316, 330 n.12 (1961).

[26] As if to make up for the inadequacy of the FTC's own grounds for broad relief, the court below proposed to add "the seriousness of potential violations" as an additional factor (Pet. App. 18a). It then cited that factor in support of two items of relief, Parts I and IV of the Order, for which the agency had given no such reason (Pet. App. 19a, 23a). This was erroneous and another transgression of the *Chenery* rule, *see* Point I *supra*.

against Sterling as against Bristol-Myers Co. and American Home Products Corp. in two companion cases, *supra,* n. 2, notwithstanding major differences among the cases. The validity of the FTC's decision and order has to be judged on the record in this case, but reference to the other cases is unavoidable for the simple reason that the order against Sterling is incomprehensible outside the context of the other cases.

Thus, the insistence upon a spurious history of past violations for Sterling, *see* Part III *supra,* was patently part of an effort to treat this case as if it were the same as the companion cases. In those cases, the relief entered against Bristol-Myers and American Home was based on their protracted histories of concealing the fact that the essential active ingredient of their products (Excedrin, Bufferin and Anacin) was aspirin and falsely claiming that they were stronger, faster or safer than aspirin.[27] In addition, both had extensive records of adjudicated violations in prior cases, to the extent that the FTC staff was "aware of no respondent . . . charged with violating Section 5 more frequently than Bristol-Myers"[28] and the Commission found "no room left to doubt that [American Home] is a habitual violator of the Federal Trade Commission Act."[29]

In contrast, Sterling has no prior record (*supra,* pp. 20-21), and it was exonerated on its central ad-

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[27] *Bristol-Myers Co.,* 102 F.T.C. at 373; *American Home Products Corp.,* 98 F.T.C. at 401. The violations were found to have been made for more than 25 years for Bufferin, more than 15 years for Excedrin and Anacin.

[28] Complaint Counsel's Memorandum in FTC Docket No. 8917, dated July 17, 1979 at 183.

[29] 98 F.T.C. at 402.

vertising claim of Bayer's overall pharmaceutical superiority over other brands of aspirin and on a large number of other points (*supra,* p. 4). In addition, as the Commission found, the disputed ads were disseminated only for a brief period in Bayer's long history, and they had no impact on the public's image of the product (Pet. App. 116a-117a). The significant disparity in facts at issue, and the extent of exoneration of Sterling as compared with its competitors, were entirely overlooked by both the Commission and the court. Clearly, however, these were "factor[s] to be weighed in judging the reasonableness" of relief. *ITT Continental Baking Co.* v. *FTC,* 532 F.2d at 221; *Standard Oil Co. of California* v. *FTC,* 577 F.2d 653, 663 (9th Cir. 1978); *Sears, Roebuck & Co.* v. *FTC,* 676 F.2d at 393.

Moreover, misrepresentation of ingredients was the pervasive advertising motif of the other two cases. This explains the entry of broad orders in those cases against claims of unusual, special or unique ingredients in any nonprescription drug product—not limited to analgesics—and against misrepresentation of analgesic ingredients in any nonprescription analgesic product. In an effort to maintain symmetry among the cases, the FTC imposed the same provisions against Sterling. But here the claim of unique ingredient was not central to Sterling's advertising but was allegedly made only in two ads for a minor product no longer on the market (Pet. App. 99a-100a; n. 7, *supra*); and the misrepresentation of an analgesic ingredient was allegedly made in only four ads for another minor product (Pet. App. 94a-96a, 98a). We believe there were *no* violations but, in any event, the sweeping relief entered by the Commission bore "no reasonable rela-

tion" to the practices found to be unlawful in this case. *Standard Oil Co. of California* v. *FTC,* 577 F.2d at 662.

In its opinion, the FTC saw "no reason to depart" from the clinical-test requirement adopted in the companion cases (Pet. App. 37a-38a). As we have shown in Point II, however, the record here was different and required a different conclusion on scientific substantiation for Bayer. Indeed, on all aspects of the order, the FTC was obliged to treat this case on its own terms and to base its order on the facts of *this* record. Instead of arbitrarily striving to attain the same result, the Commission should have taken account of the differences among the three analgesic cases. We submit that the FTC acted unreasonably and arbitrarily in subjecting Sterling to the same broad relief as in the other cases.[30]

The court of appeals erred in failing to correct this error, and in uncritically accepting the FTC decision, contrary to the record as a whole in this case.

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[30] It was error for the FTC arbitrarily to subject companies to the same broad relief, when the cases are different, just as it has been held that the agency may not treat similarly-situated parties differently, with resulting competitive detriment. *See Ford Motor Co.* v. *FTC,* 547 F.2d 954, 957-61 (6th Cir. 1976), *cert. denied,* 431 U.S. 915 (1977); *see also Chrysler Corp.* v. *FTC,* 561 F.2d 357, 364 (D.C. Cir. 1977).

CONCLUSION

For the foregoing reasons, this petition should be granted.

Respectfully submitted,

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APPENDIX

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APPENDIX

NINTH CIRCUIT'S OPINION AND ORDER DENYING PETITION TO REVERSE FTC ORDER

Dated August 28, 1984

UNITED STATES COURT OF APPEALS,
NINTH CIRCUIT.

No. 83-7700

STERLING DRUG, INC., *Petitioner*,

v.

FEDERAL TRADE COMMISSION, *Respondent*.

Argued and Submitted May 15, 1984.

Decided Aug. 28, 1984.

Drug manufacturer sought review of FTC orders dealing with advertising. The Court of Appeals, Hug, Circuit Judge, held that: (1) evidence sustained FTC finding that advertisement for various internal analgesic products was misleading, and (2) FTC order was not overly broad.

Order enforced.

* * * * * * * * *

Lionel Kestenbaum, Howard Adler, Jr., Bergson, Borkland, Margolis, & Adler, Washington, D.C., for petitioner.

Melvin H. Orlans, Regional Counsel, F.T.C., Washington, D.C., for respondent.

On Petition for Review of an Order for the Federal Trade Commission.

Before WRIGHT, HUG, and NELSON, Circuit Judges.

Hug, Circuit Judge:

In this appeal from a decision of the Federal Trade Commission, Sterling Drug, Inc. seeks review of a determination that it disseminated false advertising for its nonprescription analgesic products. Sterling contests findings by the Commission that its advertising was deceptive. It contends that the provisions of the cease and desist order are not warranted by the record and that the order applies to more of Sterling's products than is warranted by the record. We uphold the findings and enforce the order.

I

Facts and Procedural History

Sterling Drug, Inc. ("Sterling") manufactures nonprescription internal analgesic products, including Bayer Aspirin, Bayer Children's Aspirin, Vanquish, Cope, and Midol. In February 1983, the Federal Trade Commission issued an administrative complaint against Sterling in which it was alleged that certain Sterling advertisements violated sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. On the same day, the Commission also charged that two of Sterling's competitors had engaged in deceptive advertising practices. Those complaints named Bristol-Myers Company, which manufactures Bufferin and Excedrin, and American Home Products Corporation, which produces Anacin and Arthritis Pain Formula.

The cases were partially consolidated before an administrative law judge, who held joint hearings on issues common to the three cases. After extensive pretrial discovery, the ALJ held a separate hearing in this case in 1979-80. He heard testimony from forty witnesses, including experts in the fields of medicine, pharmacology, and advertising. He also reviewed hundreds of exhibits and a large volume of scientific publications submitted in conjunction with the testimony of the expert witnesses.

The ALJ found each of the companies liable for violations of the Act and issued broad cease and desist orders barring future violations. Each of the companies appealed to the Commission. In each case, the Commission affirmed the ALJ's decision as modified.[1]

In considering Sterling's appeal, the Commission reviewed a complaint against Sterling that charged deceptive advertising as to several of its products. Briefly summarized, the charges made by the complaint and the holdings reached by the Commission are as follows:

A. Advertising for Bayer Aspirin.

1. The complaint charged that Sterling had advertised that it was scientifically established that Bayer Aspirin had overall pharmaceutical superiority to other brands and that it was also pharmaceutically superior as to four specific attributes: purity, freshness, stability, and speed of disintegration.

The Commission held that the Government had not met its burden of proof on the charge that a study done by Sterling on overall pharmaceutical quality did not demonstrate Bayer's superior quality. However, the Commission held that Sterling's scientific study did not establish superior pharmaceutical quality as to the four specific attributes.

2. The complaint charged that Sterling had represented that Bayer's therapeutic effectiveness had been established by scientific means.

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[1] The Commission's order in *American Home Products* was enforced as modified in *American Home Products Corp. v. F.T.C.*, 695 F.2d 681 (3d Cir. 1982). In *Bristol-Myers Co.*, enforcement of the Commission's order was also granted on appeal. *See Bristol-Myers Co. v. F.T.C.*, 738 F.2d 554 (2d Cir. 1984).

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The Commission found that the representation had been made in the advertising and that the claim was not supported by scientifically acceptable evidence.

3. The complaint charged that advertising represented that Bayer relieved nervous tension, stress, fatigue, and depression and that there was no reasonable basis for the claim.

The Commission held that the advertising did not make this representation.

B. Advertising for Cope.

1. The complaint charged that advertising falsely claimed that Cope had a unique formula that acted as a powerful pain reliever and as a gentle relaxer.

The Commission found that the advertising made the representation and that there was no reasonable support for the claim that the formula was unique.

2. The complaint charged that advertising represented that Cope relieved nervous tension, stress, fatigue, and depression and that its effectiveness was established.

The Commission found that the representation was made and that there was no reasonable support for the claim.

C. Advertising for Midol.

1. The complaint charged that advertising represented that Midol did not contain aspirin as its analgesic agent whereas, in fact, it did.

The Commission found that a false representation had been made.

2. The complaint charged that advertising represented that Midol relieved nervous tension, stress, fatigue, and depression.

The Commission found that the representation was made and that there was no reasonable support for the claim. Sterling does not challenge this finding on appeal.

D. Advertising for Vanquish.

1. The complaint charged that Sterling claimed that Vanquish was superior to other products as a pain reliever and caused less stomach upset than other products and that this claim was scientifically established.

The Commission found that Sterling had represented that Vanquish was superior as to these qualities and that there was no reasonable basis for the claim, but the Commission also found that Sterling had not claimed that superiority was scientifically established.

E. Advertising for Bayer Children's Aspirin.

1. The complaint charged that Sterling had represented that its children's aspirin had superior therapeutic effectiveness to other products.

The Commission found that there had been no such representation.

The Commission entered a cease and desist order, which is set forth in Appendix A. All portions of the order covered the following Sterling products: Bayer, Bayer Children's Aspirin, Vanquish, Cope, Midol, or other nonprescription internal analgesic products. Paragraph IV of the order also covered all of Sterling's nonprescription

drug products. The order set forth the criteria that must be met before Sterling can claim that superior therapeutic effectiveness or pharmaceutical quality has been established scientifically. The order also set forth the standard to be met for these products where claims of therapeutic performance are made but no claims are made that such performance has been scientifically established. The order prohibited Sterling from representing that one of its products has an unusual or special ingredient when the ingredient is commonly used in other similar products. The order also restricted Sterling from representing that the analgesic agent is an ingredient different from aspirin when, in fact, it is aspirin.

II

Liability Determinations

A. Standard of Review

In reviewing the Commission's liability determinations, we apply the standard of review set out in 15 U.S.C. § 45(c): the Commission's factual findings, "if supported by evidence, shall be conclusive." This standard requires such relevant evidence as a reasonable mind might accept as adequate to support the conclusion. *Litton Industries, Inc. v. F.T.C.*, 676 F.2d 364, 368 (9th Cir.1982). Thus the reviewing court may not reweigh the evidence, but must accept the findings of the Commission, if supported by substantial evidence in the record as a whole. *See American Home Products Corp. v. F.T.C.*, 695 F.2d 681, 686 (3d Cir.1982).

The term "deceptive practices" states a legal standard, the ultimate determination of which remains with the courts; however, the Supreme Court has held that the Commission's judgment that a practice is deceptive is to be given great weight. The Court stated:

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> This statutory scheme necessarily gives the Commission an influential role in interpreting § 5 and in applying it to the facts of particular cases arising out of unprecedented situations. Moreover, as an administrative agency which deals continually with cases in the area, the Commission is often in a better position than are courts to determine when a practice is "deceptive" within the meaning of the Act. This Court has frequently stated that the Commission's judgment is to be given great weight by reviewing courts. This admonition is especially true with respect to allegedly deceptive advertising since the finding of a § 5 violation in this field rests so heavily on inference and pragmatic judgment. Nevertheless, while informed judicial determination is dependent upon enlightenment gained from administrative experience, in the last analysis the words "deceptive practices" set forth a legal standard and they must get their final meaning from judicial construction.

F.T.C. v. Colgate-Palmolive Co., 380 U.S. 374, 385, 85 S.Ct. 1035, 1042-43, 13 L.Ed.2d 904 (1965) (citations omitted).

B. Discussion

In its examination of the complaint, the Commission distinguished three distinct types of advertising claims. The first type, establishment claims, suggests that a product's superiority has been scientifically established. An advertiser may make this type of representation through the use of specific language, such as "medically proven," or through the use of visual representations.

The second type of claim is a representation that suggests the product is superior without claiming that superiority has been scientifically established. The claimed superiority may refer to therapeutic efficacy or may describe the product's pharmaceutical attributes, such as freshness, purity, color, and shelf life. The Commission

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requires that the advertiser have a reasonable basis to support a claim of product superiority.

The third type of claim is puffing. These claims are either vague or highly subjective, *e.g.*, "Bayer works wonders," and therefore no substantiation of the claim is required.

1. Findings Concerning Bayer Aspirin Advertisements

a. *Establishment of Pharmaceutical Claims*

The complaint charged Sterling had claimed that Bayer's overall pharmaceutical superiority to other brands had been established and that Bayer's superiority as to certain specific pharmaceutical attributes had also been established. Sterling contended it was entitled to make such claims because of an in-house study it conducted in 1971 that compared Bayer to 220 other brands of plain 5-grain aspirin. The study evaluated thirty pharmaceutical characteristics. Sterling contended the study established both Bayer's overall pharmaceutical superiority to all other brands and its superiority with regard to the four specific attributes listed in the Commission's order. The Commission agreed that the Government had not carried its burden of proof because it did not show the aspirin comparison study was inadequate support for a claim of overall pharmaceutical superiority. However, after analyzing the test results on specific attributes and the expert testimony evaluating those results, the Commission determined the study did not support Sterling's claims as to those individual qualities.

Sterling's first argument on this issue is that, viewed as a whole, the advertisements claimed only that Bayer had overall pharmaceutical superiority, but made no specific claim of superior freshness, purity, or stability. It relies on the testimony of its expert, Dr. Miles, who concluded these individual attributes were "buried" in the advertisements and would not be noticed by consumers.

The Commission apparently rejected the expert testimony because it believed the claim of superiority of individual attributes was clear on the face of the advertisements. It cited as an example a print advertisement that stated "Bayer tested its aspirin against every other leading brand. For purity, stability, speed of disintegration, Bayer was consistently better." The inference that this advertisement claimed better purity, stability, and speed of disintegration is not unreasonable. The Commission was careful to distinguish advertisements that asserted only overall qualtiy. We therefore reject Sterling's contention.

Alternatively, Sterling argues the Commission misconstrued the test results and ignored the testimony of its experts. The Commission's analysis as to each attribute, however, weighs the testimony of the experts and reveals the basis for the Commission's conclusions. This court may not redetermine the weight to be given Sterling's evidence. *Corn Products Refining Co. v. F.T.C.*, 324 U.S. 726, 739, 65 S.Ct. 961, 967, 89 L.Ed. 1320 (1945); *Safeway Stores, Inc.* v. *F.T.C.*, 366 F.2d 795, 800 (9th Cir.1966), *cert. denied*, 386 U.S. 932, 87 S.Ct. 954, 17 L.Ed.2d 805 (1967). We therefore affirm the conclusion that these claims were deceptive.

b. *Establishment of Therapeutic Superiority*

The Commission determined that several advertisements for Bayer Aspirin represented the product to be therapeutically superior and claimed that superiority had been scientifically established. Sterling first contends that those advertisements, read as a whole, merely claimed Bayer's pharmaceutical superiority, not its therapeutic superiority. Its second contention is that there was no establishment claim.

The Commission's conclusions were based largely on its own reading of the advertisements. It observed that the

advertisements referred to the product's "quality" without limiting or explaining that term. Because the Commission thought that consumers' primary concern was effective pain relief, it assumed that consumers would understand a representation of quality as a promise of therapeutic superiority. "[T]he ads speak in such sweeping terms about quality that a consumer could reasonably infer that the [aspirin comparison] tests measured Bayer in all respects, including efficacy."

Sterling insists this analysis ignores the findings of the ALJ, who found consumers could distinguish drug quality claims from drug performance claims. The Commission did not reject this finding. However, it held that specific advertisements would lead consumers away from distinguishing pharmaceutical from therapeutic claims because the broad language used suggested that "quality" included the attribute of effectiveness. This was especially found to be true in advertisements that also referred to pain relief or to speed of disintegration, which consumers might view as a therapeutic attribute. For these reasons, the Commission agreed with the ALJ that the advertisements made therapeutic claims.

Sterling claims the Commission improperly rejected the testimony of Dr. Miles, an expert in advertising and marketing. She testified that quality was a concept that was recognizable to consumers and that would not be confused with therapeutic effectiveness. She also stated, however, that consumers did not devote mental energy to interpreting Bayer advertisements and would not "rationally process advertising communications." The Commission did not ignore this testimony. Instead, it viewed it as evidence that, given a broad general representation of "quality," consumers would not attempt to analyze the components of quality. If the representation were so broad as to include an inference of efficacy, consumers would not consider whether any limitation had been placed on the term.

This was particularly true of advertisements that, in addition to claiming "quality," claimed aspirin was a superior pain reliever to combination products.

Among the items of evidence presented to the ALJ were "copy tests" designed to measure viewer reaction to advertisements. The tests had surveyed viewers of two Bayer advertisements and found 11 percent of the viewers of one advertisement received an efficacy message and 13 percent of the viewers of the second advertisement received such a message. The ALJ partially accepted these test results and held they supported the conclusion that certain Bayer advertisements conveyed a message of therapeutic superiority. The Commission rejected this evidence. It found that the test methodology was flawed, that the percentages were too small to be significant, and that the tests on which the ALJ relied conflicted with other copy test evidence. Sterling now argues the Commission impermissibly ignored this evidence.

The Commission can determine whether evidence is reliable and competent. *See Resort Car Rental System, Inc. v. F.T.C.*, 518 F.2d 962, 963 (9th Cir.) (per curiam), *cert. denied*, 423 U.S. 827, 96 S.Ct. 41, 46 L.Ed.2d 42 (1975). It explained fully why it disagreed with the ALJ's appraisal of this evidence. *Cf. Cinderella Career & Finishing Schools, Inc.* v. *F.T.C.*, 425 F.2d 583, 589 (D.C.Cir.1970) (Commission may not reverse ALJ's determinations without stating reasons for doing so). We therefore do not agree that this evidence was ignored.

The Commission held it did not need to consider whether Sterling had a reasonable basis to claim Bayer was therapeutically superior, since in every case Sterling had also claimed that Bayer's therapeutic superiority was scientifically established. It concluded that Sterling lacked the substantiation to make these establishment claims. The Commission held that establishment claims could be sub-

stantiated only if Sterling relied upon two well-controlled clinical studies that indicated Bayer was superior.[2]

Sterling refutes the conclusion that it made establishment claims, arguing that the text of its advertisements made no explicit assertion that Bayer's therapeutic superiority was established. However, the Commission's conclusions were based upon visual aspects of the advertisements, rather than only on the text. These visual representations included pictures of medical and scientific reports from which consumers could infer that Bayer's effectiveness had been objectively evaluated. The Commission noted that the advertisements conveyed a "serious tone" or a "scientific aura" that also implied scientific approval of the product.

A determination of false advertising can be based upon deceptive visual representations. *Standard Oil Co. of California v. F.T.C.*, 577 F.2d 653, 659 (9th Cir. 1978); *see American Home*, 695 F.2d at 688. It is within the Commission's expertise to determine what inferences consumers may draw from such representations. *See Simeon Management Corp. v. F.T.C.*, 579 F.2d 1137, 1146 & n. 11 (9th Cir.1978); *Resort Car*, 518 F.2d at 964. We defer to that expertise and affirm the conclusion that Bayer was advertised to have scientifically established therapeutic superiority.

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[2] The Commission described the required tests as follows:

> In a well-controlled clinical test, drugs are tested on real patients having actual symptoms. It is not disputed in this case that the elements of a well-controlled clinical test are the use of an appropriate pain model, replication of results, experienced unbiased investigator and adequately trained personnel, a written protocol, double-blinding, use of a placebo control, use of appropriate predetermined analytical techniques, and statistical and clinical significance of the results.

Sterling also challenges the conclusion that its establishment claims were not substantiated. It contends its in-house study comparing aspirin brands established Bayer's superior therapeutic efficacy. It therefore questions the requirement that it rely on two well-controlled clinical tests to support its advertising claims. Sterling concedes that clinical studies are necessary to compare the therapeutic effects of different drugs or of different dosages of the same drug. It argues, however, that physicians and scientists would not require clinical studies to determine the comparative therapeutic efficacy of identical drugs and dosage forms. Sterling maintains that a therapeutic judgment comparing brands of the same drug could be based on pharmaceutical and other non-clinical data. It therefore insists that its aspirin comparison study, which tended to demonstrate Bayer's pharmaceutical superiority, provided a reasonable basis to claim established therapeutic superiority.

The ALJ was provided extensive evidence on this issue, including testimony of several experts in various medical and pharmaceutical specialties and scientific literature. He took quite a narrow view of which of these items of evidence were to be accorded substantial weight. He accorded more weight to the testimony of experts specifically experienced in the comparison of mild analgesics. Sterling argues vigorously that the ALJ's evaluation of the evidence ignored substantial portions of the expert testimony. It stresses that a decision that ignores competent evidence cannot be supported by substantial evidence, citing *Cinderella Career & Finishing Schools*, 425 F.2d at 589.

We do not agree that the ALJ ignored Sterling's experts. His voluminous findings summarize each expert's testimony and evaluate the weight to be given it based on its relevance and the expert's experience. The Commission relied on the ALJ's evaluation of the evidence when it held that "it is the consensus of the experts with experience in

comparing analgesic efficacy who testified in this proceeding that at this time well-controlled clinical tests are necessary to establish the comparative superiority of one brand of aspirin over others." This is not equivalent to a finding that no evidence supported Sterling's position. It merely signifies that the Commission agreed with the ALJ's resolution of the evidentiary conflict. Because we cannot reweigh the evidence, we affirm the Commission's conclusion.

2. Findings Concerning Cope

a. *Uniqueness Claims*

Cope, which Sterling marketed as a remedy for nervous tension headaches, contained aspirin, caffeine, and methapyrilene fumarate, an antihistimine included to induce drowsiness. The Commission held this formula was falsely represented to be unique in advertisements such as this:

> Cope looks different, is different. Besides a powerful pain reliever, Cope gives you a gentle relaxer. The others don't. . . . A unique formula for really effective relief of nervous tension headache. And you get it only in Cope.

The representation was held to be false because a Bristol-Myers product, Excedrin P.M., also contained aspirin and methapyrilene fumarate. The Commission found that the misrepresentation was material because it discouraged consumers from comparing the two products.

Sterling maintains the Cope formula was unique because Cope was the only product on the market designed for daytime relief of tension headaches. It contends Excedrin P.M. was not intended for the same use as Cope; Excedrin's larger dose of methapyrilene fumerate made it appropriate only for nighttime use. Sterling argues that, unlike Cope, Excedrin P.M. was intended as a sleeping aid.

We agree with the Commission that the Cope advertisements made clear and broad claims of uniqueness that were in no way limited to Cope's intended use as a daytime remedy. Because consumers would not have been led to distinguish Cope from Excedrin P.M., the representation of uniqueness was deceptive.

b. *Establishment of Therapeutic Claims*

Sterling does not contest the Commission's conclusion that it made therapeutic efficacy claims as to Cope. However, it claims these representations did not include the assertion that Cope's superiority was established.

The Commission based its conclusion on the visual aspects of advertisements for Cope. It cited as an example a television advertisement in which an announcer discussed Cope's efficacy in conjunction with his description of "important studies" on pain relief. The announcer held a copy of the "important studies." In the background were shelves lined with "ponderous books." We agree with the Commission that the combination of the visual and oral representations was apt to convey to consumers a message of proven efficacy.

The Commission found Sterling could not substantiate its claim that Cope's therapeutic efficacy was established. Sterling does not challenge that finding on appeal.

3. Findings Concerning Midol

The complaint charged Sterling with failing to disclose Midol's aspirin content. The Commission held that a mere failure to disclose the presence of aspirin in advertising for aspirin-based analgesics was not misleading. It concluded, however, that it was a deceptive practice to disseminate advertising that implied aspirin-based products did not contain aspirin. It found that certain Midol adver-

tisements did create that impression, and it illustrated its finding with this radio advertisement:

> Midol starts to work fast with an exclusive formula that helps stop periodic pain . . . and its medically approved ingredients give effective relief from headache and low backache. All in all, Midol's unique formula gets you through those days in comfort.

The Commission concluded that the term "exclusive formula" conveyed the message that Midol's analgesic ingredient was not aspirin. It also criticized an advertisement that claimed Midol was made from an "exclusive formula with medication ordinary pain relievers don't give you."

The failure to disclose material information may cause an advertisement to be deceptive, even if it does not state false facts. *Simeon Management*, 579 F.2d at 1145; *see also Bristol-Myers Co. v. F.T.C.*, 738 F.2d 554, at 563 (2d Cir. 1984). We must reject Sterling's contention that these advertisements were not intended to suggest that Midol's analgesic ingredient was unique. The illustrative advertisements specifically state that the unique ingredient relieves pain. We agree with the Commission that consumers could easily infer the unique pain reliever was something other than ordinary aspirin.

III

Validity of the Order

A. Standard of Review

Under the Federal Trade Commission Act, the Commission has the primary responsibility for determining the remedy for deceptive advertising. *See F.T.C. v. National Lead Co.*, 352 U.S. 419, 429, 77 S.Ct. 502, 509, 1 L.Ed.2d 438 (1957). Because of the Commission's expertise in determining what remedy is required to eliminate an unfair or deceptive practice, the Commission is granted wide lati-

tude in deciding the scope of its orders. *Jacob Siegel Co. v. F.T.C.*, 327 U.S. 608, 612-13, 66 S.Ct. 758, 760-61, 90 L.Ed. 888 (1946). In drafting the Act, Congress recognized that "there is no limit to human inventiveness in [the advertising] field." *F.T.C. v. Sperry & Hutchinson Co.*, 405 U.S. 233, 240, 92 S.Ct. 898, 903, 31 L.Ed.2d 170 (1972) (quoting H.R.Conf.Rep. No. 1142, 63d Cong., 2d Sess., 19 (1914)). Accordingly, it authorized the Commission to draft orders encompassing all of an advertiser's products or all products in a broad product category in order to "fence in" known violators of the Act. *See National Lead*, 352 U.S. at 431, 77 S.Ct. at 510; *Litton*, 676 F.2d at 370. "Fencing-in provisions serve to 'close all roads to the prohibited goal, so that [the FTC's] order may not be by-passed with impunity.' " *Id.* (quoting *F.T.C. v. Ruberoid Co.*, 343 U.S. 470, 473, 72 S.Ct. 800, 803, 96 L.Ed. 1081 (1952)).

In reviewing the Commission's order, we must bear in mind its broad powers and its expertise in protecting consumers. We may not "lightly modify" the Commission's orders. *Colgate-Palmolive*, 380 U.S. at 392, 85 S.Ct. at 1046; *F.T.C. v. Cement Institute*, 333 U.S. 683, 726, 68 S.Ct. 793, 815, 92 L.Ed. 1010 (1948). Our inquiry is limited to the determinations that the order is sufficiently clear and precise to give notice to the advertiser and its scope bears a reasonable relation to the advertiser's violations of the Act. *Colgate-Palmolive*, 380 U.S. at 392, 394-95, 85 S.Ct. at 1046, 1047-48; *Litton*, 676 F.2d at 369, 370.

In *Sears, Roebuck and Co. v. F.T.C.*, 676 F.2d 385 (9th Cir.1982), we explored in depth the factors that indicate whether there is a reasonable relationship between the violation and the scope of the order. We observed that the "ultimate question is the likelihood of the petitioner committing the sort of unfair practices [the order] prohibit[s]." *Id.* at 391 (quoting *Litton*, 676 F.2d at 370). We outlined the elements on which a forecast of future violations may be based: (1) the deliberateness of the vio-

lation; (2) the violator's past record with respect to advertising practices; and (3) the adaptability or transferability of the unfair practice to other products. *Id.* at 392. We concluded that no single factor was determinative, but that the "more egregious the facts with respect to a particular element, the less important it is that another negative factor be present." *Id.*

In reviewing the Commission's order in the *American Home* case, the Third Circuit applied our analysis in *Sears, Roebuck.* Because of the nature of the products involved, the court believed it should also consider the seriousness of potential violations of the order. *American Home,* 695 F.2d at 706. It concluded that the health risks and potential adverse side effects associated with aspirin made this a unique product category. *Id.* at 698. The court also considered the fact that it is difficult for consumers to compare analgesic products effectively, so they are more likely to give credence to advertising claims. *Id.* We agree with the Third Circuit's conclusion that "[w]hen drug advertising is at issue, the potential health hazards may well justify a more sweeping order than would be proper were the Commission dealing with a less consequential area." *Id.* at 706. We therefore add the seriousness of potential violations to our analysis under *Sears, Roebuck.*

B. Discussion

1. Paragraph I of the Order

Paragraph I outlines the means by which Sterling must substantiate a claim that the therapeutic superiority of any of its nonprescription internal analgesic products is established. The order requires that such claims be supported by two well-controlled clinical studies, and it sets out the procedures under which such studies must be conducted. Section D of the paragraph authorizes an alternate method of establishing a claim of therapeutic superiority, permitting Sterling to disseminate a claim that cannot be

verified by two well-controlled clinical studies, but which is supported by a test or investigation that is generally accepted by the relevant scientific community as sufficient to establish the claim.

Sterling contends this paragraph is impermissibly broad. It argues that, at the least, the order should apply only to the two products, Bayer and Cope, as to which Sterling advertised established therapeutic superiority. We agree with the Commission that the scope of the paragraph is appropriate.

The violation was deliberate. The deceptive advertisements incorporated text, tone, and visual aspects intended to subtly persuade consumers that Bayer and Cope's therapeutic superiority had been scientifically established. These advertisements were widely disseminated for a period of several years.

The Commission found that Sterling did have a past history of violations, including an order litigated in 1950 regarding false claims that Bayer had been endorsed by a pharmacists' group. Sterling's record with the Commission also included four consent decrees involving non-analgesic products.

Applying the third *Sears, Roebuck* factor, the Commission found this practice to be readily transferable. It reasoned that if the order were limited to Bayer and Cope, Sterling could easily use the same subtle advertising devices to suggest that another internal analgesic had proven therapeutic superiority. Sterling would be free to change the name of one of its products and thereby avoid the order's restrictions.

We believe any future violation of this nature would be serious and should therefore be prevented. These advertisements convey a strong message to consumers—that doctors and scientists endorse the product—and do so in

a manner so intentionally subtle that consumers are unlikely to analyze the message they receive.

We reject Sterling's contention that the requirement of two well-controlled clinical tests is unduly burdensome. The order sets out precisely the procedures to be followed; there is no question of adequate notice to Sterling. The Commission responded to Sterling's argument that the scientific community would not demand such studies by permitting an alternate means of supporting its claims. Furthermore, Sterling's argument that these requirements are burdensome ignores the obvious. If it prefers not to undertake the burden of establishing the truth of its claims, it need only refrain from claiming its products have been proven to be superior.

2. Paragraph II of the Order

Paragraph II regulates establishment claims as to the pharmaceutical quality of any of Sterling's nonprescription internal analgesic products. It is specifically limited to claims that any such product has superior purity, freshness, stability, or speed of disintegration. The level of support required for these claims is more lenient than that imposed in Paragraph I. Sterling is required to possess and rely on scientific evidence that would satisfy relevant experts as reliable.

Stering believes this paragraph must be vacated because its establishment claims as to pharmaceutical attributes were made only about Bayer and there is no evidence it will make such claims about Bayer or any other internal analgesic in the future. We disagree. The violation was deliberate; the advertisements made explicit factual statements that consumers were likely to view as verified. *See Sears, Roebuck*, 676 F.2d at 393; *American Home*, 695 F.2d at 697. Although the challenged claims were made only as to Bayer, it is clear that these claims are easily adaptable for use in other Sterling advertisements. This para-

graph is narrowly drawn, referring only to four specific attributes, and is reasonably related to the violation. It will therefore be enforced.

3. Paragraph III of the Order

Paragraph III requires Sterling to have a reasonable basis to support therapeutic performance claims for any of its nonprescription internal analgesic products. "Reasonable basis" is defined in the order as "competent and reliable scientific evidence."

Sterling asks us to vacate this paragraph as too vague. It relies upon *American Home,* in which the court held that an identical reasonable basis requirement was too vague and imprecise to give the advertiser sufficient notice of the standard. *American Home,* 695 F.2d at 710-11. The Commission's decision in *American Home* had acknowledged that the requirement of competent and reliable scientific evidence was intended to be flexible. The Commission refused to equate the requirement with the well-controlled clinical tests standard, stating instead it would determine the standard on a case-by-case basis. *Id.* at 710. The reviewing court found that the imprecision of this standard was exacerbated by the order's overbreadth. The advertiser had made only one comparative efficacy claim, but was subjected to an order covering all of its nonprescription drug products. The court concluded the combination of overbreadth and imprecision required it to deny enforcement of that section of the order. *Id.* at 711.

The Commission again applied the "competent and reliable scientific evidence" standard in this case and in *Bristol-Myers.* In the explanation of its order, however, it attempted to make the standard more precise. It described the standard as requiring more support than the usual reasonable basis test, but less than that required for establishment claims. It recognized that this left "some

ambiguity" regarding the minimum acceptable level of support, but observed that submission of two clinical studies would always be sufficient. It concluded that the flexibility inherent in the standard set "an appropriate balance between the need for clear standards and the need to prevent repeated violations."

We agree with the Second Circuit's conclusion that *American Home* should be distinguished. *See Bristol-Myers,* at 560-61. As in *Bristol-Myers,* the order here is not overbroad, but is limited to the product category in which a violation occurred. Sterling does not contest the Commission's determination that it made therapeutic efficacy claims as to Cope, Vanish, and Midol. The Commission also found such claims were made as to Bayer. Sterling's pattern of transferring this deceptive practice from one product to another is therefore clear.

With the Commission's explanation of its intent, this section of the order is probably "as specific as the circumstances will permit." *Colgate-Palmolive,* 380 U.S. at 393, 85 S.Ct. at 1047. In view of the extent of Sterling's violations and of the fact that violations were transferred from one product to another, it is appropriate that Sterling bear any risk that results from the standard's imprecision. *Id.* If Sterling prefers to continue to advance claims of therapeutic efficacy, it can reduce its risk of violating the order in one of several ways. First, it can support its therapeutic efficacy claims with two well-controlled clinical studies. Second, it can secure from the Commission an advisory opinion as to the propriety of proposed advertising. *See id.* at 394, 85 S.Ct. at 1047. Third, it can advise consumers that its claims of therapeutic efficacy are not clearly established. *See American Home,* 695 F.2d at 695.

We conclude that this portion of the order is sufficiently clear and precise, and it will be enforced.

4. Paragraph IV of the Order

Paragraph IV proscribes dissemination of advertising that claims or implies that a product contains any special, unusual, or unique ingredient when that ingredient is used in other nonprescription products intended for the same use. This paragraph is the broadest section of the order. It covers all nonprescription drugs manufactured by Sterling, approximately 36 products.

Sterling contends there is no basis for such a broad order. It argues the Commission's finding that it had made deceptive claims of ingredient uniqueness was based only on two Cope advertisements that had limited distribution.

The Commission emphasized that this violation was deliberate. It relied on evidence that Sterling was aware when it made its uniqueness claims that a Bristol-Myers product, Excedrin P.M., had the same ingredients as Cope. Despite this knowledge, Sterling made the specific factual representation that Cope's ingredients were unique.

The transferability of this practice also influenced the Commission. In view of the ease with which Sterling could claim any of its products is composed of unique ingredients, we agree that there is significant potential for serious future violations. Claims of this type deceive consumers as to the product's contents and defeat consumer efforts at product evaluation and comparison. They therefore encourage unnecessary use of a potentially hazardous product. *See Bristol-Myers*, at 564; *American Home*, 695 F.2d at 707.

Although the product category covered by this section is broad, the proscription is narrow and explicit. Because a very specific type of advertising claim is barred, the burden on Sterling is not onerous. The deliberateness of the violation and the serious implications of its transferability convince us that a broad order is warranted. This paragraph will therefore be enforced.

5. Paragraph V of the Order

Paragraph V prohibits Sterling from falsely representing that an aspirin-based product is different from aspirin and from misrepresenting the analgesic ingredient of any product. This section bars Sterling from creating the impression that the analgesic ingredients in its products are different from those in competing products. It also proscribes advertisements that contrast with aspirin the ingredient in an aspirin-based analgesic, without disclosing the aspirin content of the Sterling product. This paragraph covers all of Sterling's nonprescription internal analgesic products.

Sterling argues this section is irrationally broad because its violation was de minimus. We agree with the Commission, however, that this violation was serious for two reasons. First, misleading consumers who cannot tolerate aspirin is a grave concern. Second, consumers who did not know Midol's analgesic ingredient was aspirin might not question Midol's comparatively high retail price.

Moreover, the Commission carefully tailored this section of the order. The ALJ's proposed order would have required Sterling to disclose the presence of aspirin in any advertisement for an aspirin-based analgesic. The Commission rejected this requirement, holding Sterling has no affirmative duty to announce its products' aspirin content. Instead, the duty imposed by the Commission's order is that Sterling refrain from creating the false impression that a product does not contain aspirin.

Finally, Sterling argues that it has been forthright in revealing the aspirin content of Cope and Vanquish and that this indicates the violation will not be transferred to other products. If it is in fact Sterling's policy to disclose its products' aspirin content, this section of the order will not be burdensome. It is closely tailored to the practice actually committed by Sterling and is a necessary and

appropriate means of protecting consumers. Paragraph V will therefore be enforced.

The Commission's order is ENFORCED.

Appendix A

ORDER

I

IT IS ORDERED that Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or other nonprescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

Making any representation, directly or by implication, that a claim concerning the superior effectiveness of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness that it is represented to have, and (2) that such comparative effectiveness is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. The investigations shall be conducted in accordance with the procedures set forth below.

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness

of the drug shall be conducted on any disease or condition referred to, directly or by implication, or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

A. The subjects must be selected by a method that:

1. Provides adequate assurance that they are suitable for the purposes of the investigation, and the diagnostic criteria of the condition to be treated (if any);

2. Assigns the subjects to the test groups in such a way as to minimize bias; and

3. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity or duration of disease or condition (if any), and use of drugs other than test drugs.

B. The investigations must be conducted double-blind, and methods of double-blinding must be documented. In addition, the investigations shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

C. The plan or protocol for the investigations and the report of the results shall include the following:

1. A clear statement of the objective of the investigation;

2. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subject's response and steps taken to minimize bias on the part of the subject and observer;

3. A comparison of the results of treatments or diagnosis with a control in such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data;

4. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

D. A test or investigation which is not conducted in accordance with these procedures may be used to establish a claim only if respondent can show that, notwithstanding the failure to satisfy these procedures, the test or investigation would still be generally accepted by the relevant scientific community as sufficient to establish the truth of the claim.

II

IT IS FURTHER ORDERED that respondent Sterling Drug, Inc., a corporation, its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, that the superior freshness, purity, stability, or speed of disintegration of such product has been established, demonstrated, or proven unless at the time such representation is made, respondent possesses and relies upon competent and reliable scientific evidence which would

permit qualified experts to conclude that the product has the comparative pharmaceutical qualities it is represented to have.

III

IT IS FURTHER ORDERED that respondent Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription internal analgesic, in or affecting Commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any therapeutic performance claim for such product unless respondent possesses a reasonable basis for making that claim. A reasonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth in Order Paragraph I shall be deemed to constitute a reasonable basis for a claim.

IV

IT IS FURTHER ORDERED that respondent Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription drug product in or affecting commerce, as "commerce" and "drug" are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication that such

product contains any unusual, special or unique ingredient or ingredients when such ingredient or ingredients are commonly used in other nonprescription drug products intended for the same use or uses as the product advertised by respondent.

V

IT IS FURTHER ORDERED that respondent Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription internal analgesic in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin or otherwise misrepresenting the identity of any analgesic ingredient. It shall be a violation of this paragraph to contrast the analgesic ingredient of a product which contains aspirin with the analgesic ingredient of another product if that product also contains aspirin, unless respondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin.

VI

IT IS FURTHER ORDERED that respondent Sterling Drug, Inc., shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in its corporation which may affect compliance obligations under this Order.

VII

IT IS FURTHER ORDERED that the respondent herein shall within sixty (60) days after service of this Order upon it and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which it has complied or intends to comply with this Order.

COURT OF APPEALS ORDER DENYING PETITION FOR REHEARING

Dated October 29, 1984

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

No. 83-7700

FTC No. 8919

STERLING DRUG, INC., *Petitioner,*

v.

FEDERAL TRADE COMMISSION, *Respondent.*

ORDER

On Petition for Review of an Order
For the Federal Trade Commission

[Filed Oct. 29, 1984, Phillip B. Winberry, Clerk,
U.S. Court of Appeals]

Before: WRIGHT, HUG, and NELSON, Circuit Judges.

The panel as constituted in the above case has voted unanimously to deny the petition for rehearing. Judges Hug and Nelson have voted to reject the suggestion for a rehearing en banc, and Judge Wright recommends rejection of the suggestion.

The full court has been advised of the en banc suggestion and no judge of the court has requested a vote on it. Fed. R. App. P. 35(b).

The petition for rehearing is denied and the suggestion for a rehearing en banc is rejected.

FTC OPINION AND FINAL ORDER

Dated July 5, 1983

Opinion of the Commission

BY CLANTON, *Commissioner.*

I. Introduction

The American Indians knew that you could make a medicine for treating pain from the leaves and bark of the willow tree. However, it was not until the mid-1800's that acetylsalicylic acid (a substance similar to the salicin contained in willows) was synthesized and at the end of the 19th century it was first marketed commercially under the trade name "Aspirin" by the German concern, Farbenfabriken Bayer AG. During World War I the United States government seized Bayer's American assets and these (including the "Bayer" name) were sold in 1918 to Sterling Drug, Inc. ("Sterling"). At about the same time, the patent on the manufacturing process expired and shortly thereafter Sterling lost the "Aspirin" trademark in private litigation.[1]

Nonetheless, for many years, Bayer aspirin ("Bayer") remained the nation's leading over-the-counter ("OTC" or nonprescription) analgesic (pain reliever). In recent years, competition from other aspirin and acetaminophen-based analgesics has eroded Bayer's market share to the point that it is no longer the market leader. In order to stave off this decline, Sterling has devoted a substantial amount of money to advertisements for its aspirin. In fact, from 1967 through 1973, Sterling spent $118.5 million on television advertising for Bayer.

In 1973 the Commission issued a complaint against Sterling (and its two advertising agencies, Dancer-Fitzgerald-

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[1] *Bayer Co. v. United Drug Co.*, 272 F. 505 (S.D. N.Y. 1921).

Sample, Inc., and Lois Holland Callaway, Inc.) charging that advertising for Bayer and for four other analgesic products manufactured by Sterling (Bayer Children's Aspirin, Cope, Vanquish, and Midol) violated Sections 5 and 12 of the Federal Trade Commission Act (15 U.S.C. 45, 52).[2] Specifically, the complaint charged that respondents made the following false, deceptive, or unfair claims:

1) Bayer is therapeutically and qualitatively superior to any other aspirin and this superiority has been shown by tests (Comp. ¶¶ 10(A), 20), and the therapeutic superiority has been established (Comp. ¶ 8(A)(1);

2) Bayer Children's Aspirin is therapeutically superior to any other children's aspirin (Comp. ¶ 10(B)), and this superiority has been established (Comp. ¶ 8(A)(2));

3) Vanquish is a more effective pain reliever than aspirin, buffered aspirin, or the largest selling extra strength tablet (Comp. ¶ 12(B)(1).(C)), and this superiority has been established (Comp. ¶¶ 8(B)(1), (C);[3]

4) Cope is more effective for the relief of "nervous tension headache" than any other OTC internal analgesic

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[2] On the same date, the Commission issued a complaint against American Home Products regarding its advertising of Anacin and Arthritis Pain Formula and a complaint against Bristol-Myers Company regarding its advertising for Bufferin, Excedrin, and Excedrin P.M.

[3] Complaint paragraph 8(C) does not specifically allege that respondents represented that Vanquish's superior efficacy over the leading "extra-strength" tablet has been established. However, since it appears that it was complaint counsel's intent to allege establishment, and since it appears to have been the parties' understanding that establishment had been alleged (*see* Contested Issues of Fact ¶¶ 2(d), 2(e), 2(f) and since the issue was tried by the parties (*see* p. 89 of the Initial Decision), we will treat this issue as though it had been appropriately pleaded (*see* F.T.C. Rules of Practice Section 3.15(2), 16 C.F.R. 3.15(2)).

(Comp. ¶ 12(A)), this superiority has been shown by tests (Comp. ¶ 18), and this superiority has been established (Comp. ¶ 8(A)(3));

5) Vanquish will result in less stomach upset than any other unbuffered OTC analgesic (Comp. 12(B)(2)), and this superior freedom from side effects has been established (Comp. ¶ 8(B)(2));

6) Bayer, Cope, and Midol can relieve nervous tension (Comp. ¶ 15);

7) Cope is the only OTC analgesic containing both a pain reliever and a sedative (Comp. ¶ 22);

8) The analgesic in Midol is other than ordinary aspirin and its stimulant is other than caffeine (Comp. ¶ 26).

The complaint also alleged that respondent's ads failed to disclose that Vanquish, Cope, and Midol contain aspirin and caffeine (Comp. ¶¶ 23, 24, 25) and that ads for Bayer, Vanquish, and Cope made mutually inconsistent claims regarding the superior effectiveness of Bayer and Cope for the relief of "nervous tension headache," and the freedom from side effects of Bayer and Vanquish (Comp. ¶ 17).

Dancer-Fitzgerald-Sample, Inc. was charged with responsibility for all ads relating to Bayer, Bayer Children's Aspirin, and Cope. Lois Holland Callaway, Inc. was charged with responsibility for some of the ads relating to Vanquish.

This case was assigned to Administrative Law Judge Montgomery H. Hyun,[4] who reached an initial decision on January 30, 1981, finding against Sterling on all charges except for the charge related to the making of inconsistent

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[4] The companion cases against American Home Products Corp. and Bristol-Myers Company were also heard by Judge Hyun.

claims. The advertising agency, Dancer-Sample-Fitzgerald, Inc., was dismissed by Sterling in 1976 and entered into a consent order settling the charges against it. 96 F.T.C. 1 (1980). Lois Holland Callaway, Inc. became insolvent and its creditors' committee chose not to defend in this suit. The ALJ found that the ad agency had adequate substantiation for the comparative efficacy and safety claims it made regarding Vanquish, but he found it liable for failing to disclose the presence of aspirin in Vanquish.

This matter is now before us on the appeal of both respondent Sterling and complaint counsel. Sterling's principal contentions on appeal are:

1) the ALJ erred in finding that Sterling's ads made representations of therapeutic superiority;

2) the ALJ applied inappropriate substantiation standards to the ads;

3) contrary to the ALJ's decision, the nonclinical evidence in the record provides a reasonable basis for the conclusion that Bayer is pharmaceutically and therapeutically superior to other aspirin;

4) the ALJ erred by excluding scientific materials proffered by Sterling; and

5) the order entered by the ALJ is overbroad.

Complaint counsel support the ALJ's order but argue that it should be broader. Specifically, they argue:

1) the order should require the same amount of substantiation for superior quality claims as for therapeutic superiority claims;

2) the order should have broader product coverage;

3) the order should define the substantiation necessary for noncomparative tension claims;

4) corrective advertising should have been required;[5] and

5) Sterling should have been prohibited from making mutually inconsistent performance claims for its products.

Although many of the issues in this case are similar to those recently considered by the Commission in *American Home Products,* 98 F.T.C. 136 (1981), *aff'd,* 695 F.2d 681 (3rd Cir. 1982), and *Bristol-Myers,* Docket No. 8917 (1983) [102 F.T.C. 21], there are some notable differences. As the Commission noted in *American Home Products,* 98 F.T.C. at 362, because aspirin is so homey and commonplace, "a maker of one aspirin-based pain reliever seeking to differentiate its product from the rest faces a formidable marketing task." In order to accomplish this task, both American Home Products and Bristol-Myers attempted to dissociate their products from aspirin and then represent them as special and more effective. Sterling took a different approach. The advertising for Sterling's principal product, Bayer, specifically emphasizes the aspirin content of that product and its superiority over other aspirin-based analgesics. Rather than trying to disguise the aspirin ingredient,[6] respondent's ads trumpet the fact that Bayer contains aspirin and that, based on tests of competing products, Bayer is the best aspirin on the market. Sterling emphasizes that its advertising for Bayer benefitted the public because it was the only defender of aspirin. It argues that its ads countered "the tremendous volume of

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[5] Although complaint counsel indicated they did not intend to press the corrective advertising issue (Transcript of Oral Argument p. 27), they did brief this issue and we have dealt with it in this opinion (*infra* pp. 60-61).

[6] While there are allegations of failure to disclose aspirin content for Midol, etc., those issues are secondary here to the principal claims involving Bayer.

advertising" for combination products which "disparag[ed] aspirin." (Transcript of Oral Argument p. 13) Among these "disparaging" ads placed by Bayer's competitors are ads challenged in *American Home Products* and *Bristol-Myers*. Sterling further contends that its advertising was designed to show that the combination products all contained aspirin and that Bayer was as effective as any of them.

The Commission, of course, does not dispute the value of providing consumers with specific product information, especially information which facilitates product comparison. In fact, we encourage that kind of advertising.[7] The issue here, however, is whether Sterling's advertising made certain claims and whether those claims were supportable. In particular, a principal, and unique, focus of this proceeding concerns the extent to which general therapeutic superiority claims can be inferred from representations expressly referring to particular product attributes such as purity, freshness and speed of disintegration. Respondent argues that these ads make only manufacturing quality claims and that manufacturing quality is distinct from therapeutic superiority.[8] As we discuss more fully below, we believe that some of respondent's ads do make therapeutic superiority claims and references to scientific tests in those ads imply that the superiority of Bayer (and Cope) has been established.[9]

In connection with these claims of established therapeutic superiority, we find no reason to depart from our

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[7] Indeed, we find ads such as CX 31 unobjectionable.

[8] For a discussion of the difference between manufacturing quality and therapeutic superiority, *see infra* pp. 11-12.

[9] The meaning of "establishment" claims is discussed in *American Home Products*, 98 F.T.C. at 373-376 and in *Bristol-Myers*, slip op. at 18-19 [102 F.T.C. at 331-332].

conclusions in *Bristol-Myers* and *American Home Products* that these claims must be supported by well-controlled clinical studies, evidence which Sterling lacked in this case. We also find that some of the separate product attribute claims (or pharmaceutical quality claims) made by Sterling were misleading in light of the evidence relied upon to support those representations. Finally, our decision addresses a variety of other charges concerning noncomparative tension relief claims, unusual ingredient claims and material omission claims that are similar to issues considered in our other analgesic cases. We do note, at this point, two additional differences between this case and those involving Sterling's competitors, Bristol-Myers and American Home Products. Unlike those cases, the complaint in this matter includes allegations that respondent's therapeutic superiority claims lacked a reasonable basis. Another allegation, unique to this case, is that some of respondent's advertising claims were mutually inconsistent. Complaint counsel contend this practice should constitute a separate violation of the Section 5 of the F.T.C. Act.[10]

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[10] The following abbreviations are used in this opinion:

F.	—	Initial Decision, Finding No.
I.D.	—	Initial Decision
CX	—	Complaint Counsel's Exhibit No.
RX	—	Respondent's Exhibit No.
Tr.	—	Transcript of Testimony, Page No.
C.A.B.	—	Complaint Counsel's Appeal Brief
C.An.B.	—	Complaint Counsel's Answering Brief
R.A.B.	—	Sterling's Appeal Brief
R.An.B.	—	Sterling's Answering Brief

II. Comparative Efficacy and Side Effects Claims

A. The Advertisements.

Paragraphs 8-14 and 18-21 of the complaint allege that respondent Sterling made comparative performance and freedom from side effects claims for Bayer, Bayer Children's Aspirin, Vanquish, and Cope and that these claims were not properly substantiated. In discussing these allegations, we first review respondent's advertisements. It is well settled that the Commission can interpret the meaning of advertisements without necessarily referring to extrinsic evidence. *Bristol-Myers,* slip op. at 4 [102 F.T.C. at 319], *The Kroger Company,* 98 F.T.C. 639, 728 (1981). However, when extrinsic evidence is presented to assist in interpreting ads, that evidence must be considered. *Cinderella Career and Finishing Schools, Inc.* v. *F.T.C.,* 425 F.2d 583, 588 (D.C. Cir. 1970). Accordingly, we have examined all the evidence which has been presented including the ads themselves, expert testimony and copy test results. Additionally, when interpreting advertisements, we consider the net impression made by the ad. *American Home Products* v. *F.T.C.,* 695 F.2d at 687; *Beneficial Corp.* v. *F.T.C.,* 542 F.2d 611, 617 (3rd Cir. 1976), *cert. denied,* 430 U.S. 983 (1977). Therefore, we analyze each challenged advertisement as a whole.[11]

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[11] In interpreting ads, the Commission is concerned not only with representations conveyed by literal statements, but also with representations reasonably implied by the ads. However, we may not inject novel meanings into ads and then condemn them as unsupported. If an ad conveys more than one reasonable meaning and any one of these meanings is false, that ad may be found in violation of the law. Bristol-Myers, slip op. at 4-5 [102 F.T.C. at 319-320].

Challenged claims must also be material, *i.e.,* likely to influence consumers' purchasing decisions. In this case respondent has not raised any argument regarding materiality. False superiority

Sterling argues that its ads must also be examined in light of the advertising of its competitors to which it was attempting to respond. (R.A.B. p. 5) Although such a comparison may be helpful in interpreting advertising, it cannot excuse the failure to adequately substantiate the claims which are clearly made in Sterling's ads. Sterling is accountable for the advertising which it promulgated, *see Chrysler Corp.*, 87 F.T.C. 719, 752 n. 43 (1976), and it cannot justify its failings by pointing to the conduct of its competitors. (Indeed, we have already found two of its major competitors in violation of the law.)

The complaint against Sterling alleges that it made eight comparative superiority claims for Bayer, Bayer Children's Aspirin, Vanquish and Cope. The ALJ found that Sterling's ads made all eight of the claims. In addition, the complaint alleges Sterling represented that seven of these claims had been established and the ALJ also found all seven establishment representations had been made. We agree with the ALJ that Sterling's ads make some of the alleged representations and we further agree that three of the comparative claims are represented as having been established. However, we find that some of the ads cited by the ALJ as making certain representations do not make those representations. Further, as we indicated above, we disagree with the ALJ's conclusion that every ad which makes a comparative superiority claim represents that the superiority has been established.

As we described in *Bristol-Myers*, slip op. at 6 [102 F.T.C. at 321], the complaints in these cases require us to distinguish three distinct types of comparative efficacy and

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claims are material because they may discourage consumers from shopping for less expensive and potentially equally effective alternatives. (*See* F. 11) Unsubstantiated tension-relief claims are material because they may encourage excessive use of aspirin, a potentially harmful drug, or otherwise discourage consumers from purchasing more effective products.

freedom from side effects claims. The first group consists of "establishment claims," or claims that superiority has been scientifically *established*. This kind of representation may be made through the use of specific language, such as "medically proven" or through the use of visual aids, such as scientific charts and white-coated technicians. *See American Home Products*, 98 F.T.C. at 374-375. The second type consists of claims of superiority without any indication superiority has been established. An advertiser must possess a reasonable basis for making this type of claim. *See Pfizer, Inc.*, 81 F.T.C. 23 (1972) The third type of claim is puffing, for which no substantiation is required. Puffing claims are usually either vague or highly subjective and, therefore, incapable of being substantiated.[12] Each of respondent's claims can be placed in one of these three groups and the substantiation necessary is dependent upon that characterization.

1. *Claim that Bayer is therapeutically superior to any other aspirin.*[13]

Paragraph 10(A) of the complaint alleges that Sterling represented in its advertisements that Bayer is therapeutically superior to any other aspirin. The ALJ found that Sterling's ads made this claim. We agree with respect to some of the advertisements, but disagree with respect to others.

In evaluating Sterling's advertisements, it is important to understand the relationship between therapeutic effectiveness and "manufacturing quality" (also referred to as "pharmaceutical quality" or "product quality"). Therapeutic effectiveness refers to the medical effects of a drug—

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[12] The claim "Bayer works wonders" in CX 27 is an example of puffing.

[13] Complaint paragraphs 8(A)(1) and 10(A).

EDITOR'S NOTE

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its effectiveness as a pain reliever, its freedom from unwanted side effects, and so on. By contrast, manufacturing or pharmaceutical quality refers to the care with which a product containing the drug was manufactured—*e.g.*, its purity (freedom from contaminants), any tendency of the pills to crumble or deteriorate over time, or the ease with which the pills can be dissolved. A recurring issue in this case is whether Sterling's ads made claims of superior therapeutic effectiveness, or whether they claimed only superior manufacturing quality.

We agree with the ALJ that Sterling made representations of therapuetic superiority in some instances. For example, CX 161 states:

> . . . Bayer tested its aspirin for quality against the other leading brands . . . 220 brands in all. 30 separate tests were conducted in 14 different categories. . . . During the 4-year study, tests were made for purity, freshness, speed of disintegration, aspirin content, tablet count, overall quality control.
> The results were clear. Bayer was consistently superior. . . .

For several reasons we believe this ad represents that Bayer is therapeutically superior. First, the ad implies Bayer disintegrates faster than the other tested aspirins. As we discussed in *Bristol-Myers*, slip op. at 7 [102 F.T.C. at 322], consumers could reasonably infer that an aspirin that disintegrates faster provides relief faster. Since consumers want relief from pain as rapidly as possible, a pain reliever that works faster would reasonably be considered by consumers to be more effective.

Second, the reference to speed of relief is supplemented by the comprehensive nature of the comparative study. The ad emphasizes that 30 separate product attributes were tested. Although only six of those attributes are specifically mentioned, consumers could reasonably as-

sume that some of those tests related to product effectiveness not only because of the reference to speed of disintegration but also because of the clear statement that a wide variety of attributes was tested. After all, in purchasing aspirin, consumers are primarily concerned that the product purchased be able to relieve pain.

Respondent argues that this ad and others like it (*e.g.*, CX 47, 48, 79, 109, 155-158) actually discuss manufacturing quality and that speed of disintegration is just another attribute of manufacturing quality. It is true that these ads do mention specific product attributes (such as shelf life) that are not necessarily synonymous with a product's comparative therapeutic efficacy. Nevertheless, the ads refer to product characteristics, such as speed of disintegration, that are closely related to efficacy. In addition, the ads speak in such sweeping terms about quality that a consumer could reasonably infer that the tests measured Bayer in all respects, including efficacy. Certainly nothing in the ad indicates that the tests were limited to attributes relating to manufacturing quality. It is hardly reasonable to expect consumers to guess, without any prompting, that Bayer's tests of aspirin "for quality" omitted the very attribute (efficacy) that consumers value the most.

Respondent also argues that testimony of its expert witness, Dr. Miles, indicates that these ads only make representations regarding quality. (R.A.B. p. 8) We have examined Dr. Miles' testimony and find that although she said she reviewed all of the challenged ads (Tr. 9258), she only discussed one of the ads listed above, CX 157. (Tr. 9331-33) Dr. Miles did state that she believed the ad made an "unambiguous quality representation." (Tr. 9332) Nevertheless, it was her opinion that consumers reading (or viewing) an ad such as this one would not infer a message of superior efficacy because consumers do not devote much mental effort to ads: "As I said before,

they don't make inferential leaps. They don't do a lot of processing of advertising claims. They don't rationally process advertising communication." (Miles, Tr. 9311, 9333)[14] However, we believe that this analysis actually leads in the opposite direction. Efficacy is the most important feature of an analgesic, and a test of numerous product attributes designed to measure product "quality" would normally be assumed to test efficacy. Only upon application of substantial mental effort (effort which Dr. Miles believed the viewer was unlikely to apply) would it occur to a consumer that none of the tests mentioned in the ad directly measured therapeutic efficacy, and that perhaps effectiveness was *not* tested. Thus, we find that these ads[15] do represent that Bayer is therapeutically superior to other aspirin.

The ALJ also found that a representation of therapeutic superiority was made by advertisements claiming that Bayer was the best pain reliever or the best aspirin. (F. 294(b)) Once again, we agree that the representation was made at least by some of the ads cited in the ALJ's decision, although we place less reliance than did the ALJ on the ads' closing tag line. For example, CX 52 is a television ad featuring golfer Lee Trevino. He first describes an AMA study which indicates that aspirin is preferred *over combination products* for relief of pain (*i.e.*, on grounds of therapeutic efficacy). After referring to a separate study on aspirin performed by Bayer, he states, "You see, Bayer tested its aspirin for quality, for purity and for freshness against 220 other brands. The tests showed that Bayer makes the superior aspirin." The ad closes with the tag line, "Aspirin is the best pain reliever. And Bayer is the best aspirin." Because of the emphasis in the ad on the

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[14] Dr. Miles indicated that consumers did not devote mental effort to the Bayer ads because they were boring, poorly made, dull, and not memorable. (Tr. 9259, 9273, 9295, 9303, 9304, 9309)

[15] CX 47, 48, 79, 109, 155-158, 161.

AMA report and the comparative aspirin study, consumers could naturally assume that the comprehensive comparative testing performed by Sterling included tests of relative effectiveness. This inference is especially likely given the fact that Sterling's test is mentioned in the context of the AMA report, which implies that aspirin is more effective than other pain relievers. The tag line at the end of the ad does nothing to alter the impression of therapeutic superiority created by the entire ad.

Respondent argues that the "Bayer is the best aspirin" portion of the tag line is puffing which consumers would not take seriously. To support this, it cites Dr. Miles (RAB p. 9-12). However, what Dr. Miles says is that the phrase "world's best aspirin" is puffery and the phrase, "best [aspirin], all by itself is not likely to lose its puffery characteristic and take on some kind of superior therapeutic meaning." (Miles, Tr. 9271) We agree with this. Indeed, we find that in ads such as CX 13 the phrases, "Bayer works wonders," are merely puffing because the ad does not discuss any comparison of Bayer's "quality" with other brands of aspirin.[16] CX 52 is different. That ad mentions the AMA report and the Sterling test comparing 220 brands of aspirin. The tag line does not appear "all by itself," but appears in a context which invites the viewer to conclude that Bayer is therapeautically superior to other aspirin.[17]

Respondent also argues that the two parts of the tag line should be analyzed separately. It argues that the "Bayer is the best aspirin" portion of the tag line should be considered only in light of the study comparing Bayer

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[16] *See also*, CX 15, 19, 37, 38, 39, 117, 122, 123, 126, 145, 146, 147, 150, 152.

[17] Other similar ads which imply therapeutic superiority and contain the tag line are CX 50, 54, 56-64, 67-70.

to other aspirin. Although respondent would apparently agree that AMA study involved comparative efficacy, it argues that the Bayer study concerned pharmaceutical or manufacturing quality only and that, therefore, the "Bayer is the best aspirin" tag line implies only pharmaceutical superiority.

We recognize (along with the ALJ, F. 322) that pharmaceutical or manufacturing quality is an attribute of analgesics which may, in some circumstances, be distinct from therapeutic quality. But since consumers buy aspirin only to reduce fever, alleviate pain or lessen inflammation, quality, the ability of a product to do what it is supposed to do, is closely linked to efficacy. In ads such as CX 52 and others which mention Sterling's test of 220 brands of aspirin, no effort has been made to limit the claim to non-therapeutic quality characteristics.[18] Each of these ads implies that Sterling's comparative testing was comprehensive by virtue of both the number of brands and variety of attributes tested. As we mentioned before, the natural inference is that efficacy, the most important feature of any analgesic, was also tested. Although these ads do speak of "quality," that term has not been limited to non-therapeutic quality. Thus, we do not agree with respondent that the mention of Bayer's superiority in the 220 test refers only to quality attributes distinct from efficacy.

However, we do not mean by our decision to prevent Sterling from conveying information regarding Bayer's pharmaceutical or manufacturing quality. Indeed, we recognize that this information may be valuable to consumers. And, even though pharmaceutical quality is closely linked to therapeutic quality, it is certainly possible to convey information limited to non-therapeutic quality attributes.

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[18] Other similar ads which imply therapeutic superiority are CX 73-78, 80-83, 105-108, 110-116, 162, 163.

For example, CX 72 states in part, "Sometimes you can even smell a difference in aspirin. If you sense a vinegary idor, that's a sign of possible deterioration. So to get the best quality aspirin, always get Bayer." This ad discusses a particular attribute of product quality, shelf life, that consumers would understand as distinct from therapeutic superiority.[19] Although representations of superior "quality" will usually imply therapeutic superiority, that is not so with respect to CX 72 because it carefully defines product quality in terms of shelf life and thereby avoids making any representation regarding therapeutic superiority.

Respondent finally argues that it was improper for the ALJ to rely upon copy test results (F. 300-302) because the Zeisel Study (CX 520) to which he referred was flawed and because it showed that only a small percentage of consumers (11% for one ad and 13% for another) received a superior efficacy message from two of the ads (CX 52, 157) in question. (RAB p. 13 n. 20) The ALJ did, in fact, find that the Zeisel Study was flawed and that the questions asked of test participants were leading. For this reason, he rejected the results of all but the first two questions asked of participants. (F. 201) Furthermore, the only two questions which the ALJ found unobjectionable direct participants to the ad's major point. For this reason, it appears unlikely that the study would capture inferences and additional meanings drawn by consumers from the ad. Thus, the Zeisel Study cannot confirm respondent's interpretation of the ads. Indeed, another copy test in the record, CX 568 (performed by Audience Studies, Inc.), evaluated CX 50, an ad similar to CX 52. It showed that more than 22% of test participants drew a message of superior efficacy from the ad. On balance, the copy test

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[19] A product with a longer shelf life may well be no more efficacious than one with a shorter shelf life. However, it will maintain its quality for a longer time.

evidence is not especially helpful because the Zeisel Study was flawed and because its results were contradicted by CX 568. However, in this instance, the representation of Bayer's therapeutic superiority flows clearly and logically from the ads. Therefore, copy tests were not necessary to aid in our interpretations.

2. *Claims that Bayer's therapeutically superiority to any other aspirin is established.*

Paragraph 8(A) of the complaint charges Sterling with having represented that the truth of the therapeutic superiority claims for Bayer had been established. The ALJ concluded that every ad which made a representation of superior therapeutic efficacy also made an establishment claim, because consumers believe scientific evidence supports every claim of superiority regarding drugs. While we reject the ALJ's reasoning, we reach the same conclusion regarding the advertisements at issue in this case.

Respondent argues there is no justification for the ALJ's conclusion that any ad which makes a therapeutic superiority claim necessarily represents the claim is scientifically established. Sterling notes that a substantial number of ads cited by the ALJ do not mention tests at all, and those ads which do mention tests of Bayer indicate that only quality attributes were tested. (RAB pp. 14-17)

In *Bristol-Myers*, the record did not contain sufficient evidence to sustain the argument that consumers believed that every claim of superiority for an analgesic drug has been established to the satisfaction of the scientific community. Slip op. at 40-41 [102 F.T.C. at 350-351]. For the same reason—since no additional evidence has been presented in this case—we reach the same conclusion here. Nevertheless, as we also stated in *Bristol-Myers*, consumers *would* reasonably infer that a proposition in an ad has been scientifically established if the ad uses language

or visual aids which suggest such a foundation. *Id.* at 6 [102 F.T.C. at 321]. Indeed, in this case all of the challenged ads in which we find a representation that Bayer is therapeutically superior include language and pictures which suggest Bayer's therapeutic superiority has been proven. All of the ads rely heavily on the AMA report and/or Bayer's own tests.

In *Pfizer*, the Commission found that the challenged ads portrayed a frivolous aura and thus, even though the ads mentioned tests, they did not convey serious scientific overtones. 81 F.T.C. at 59. Here, the opposite is true. Not only are the challenged ads serious in tone but also the format of the ads listed above generally consists of objective evaluations (based on tests) of Bayer's superiority, thus contributing to the scientific aura of these ads. In the ads which mention speed of disintegration, the impression that tests support Bayer's superiority is enhanced by a picture of the AMA report (*e.g.*, CX 155, 156) or by a picture of a booklet containing the results of Sterling's aspirin comparison tests (*e.g.*, CX 47, 48, 157, 158, 161). Even in those instances in which the ads do not mention speed of disintegration, the ads do indicate that Sterling's testing was comprehensive, in terms of both the number of brands included and the number of attributes tested. As discussed above (*supra* pp. 11-12), the natural inference is that these tests measured efficacy and demonstrated Bayer's superiority.[20]

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[20] We do not mean to suggest that every reference in an ad to a study or test necessarily implies that the underlying claim has been scienifically proven or established. (Indeed, *Pfizer* itself is sufficient to disprove this notion.) What we do suggest is that where scientific evidence is cited in support of a claim, absent some explicit qualification it is unlikely that consumers would interpret such evidence narrowly to provide proof for only a limited portion of the claim

3. *Claim that Bayer has been tested and found pharmaceutically and therapeutically superior to all other aspirin tested.*

Paragraph 20 of the complaint alleges that respondent's ads represent that Bayer has been tested against 220 other brands of aspirin for quality, purity, freshness, stability, and speed of disintegration and that the tests demonstrate that Bayer is superior to the other brands in all these categories. The ALJ found that advertising for Bayer represented it was superior in overall quality and superior with respect to each of the other four listed attributes. We agree.

Numerous ads discuss the results of tests comparing Bayer with other aspirin. All of those ads indicate that Bayer was compared for quality against other aspirin.[21] The clear message is that the tests showed Bayer to be superior. For example, CX 108 states, "Bayer tested its aspirin for quality against all major brands of aspirin. And Bayer came out way ahead for quality." Other ads use such language as: "For quality—Bayer was shown superior" (CX 76), "The aspirin that tested better for quality" (CX 74), "Bayer was consistently better" (CX 109). In addition, some of the ads that mention the comparison mention specific attributes that were tested: purity (*e.g.*, CX 61, 79, 109), freshness (CX 47, 73, 155), stability (CX 79, 156, 158), and speed of disintegration (CX 48, 109, 157). Although the ads do not directly state that the tests showed Bayer superior for any specific attribute, superiority with respect to these attributes is clearly implied by the ads. For example, CX 79 states, "Bayer tested its aspirin against every other leading brand. For purity, stability, speed of disintegration, Bayer was consistently

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[21] The tests comparing Bayer with other aspirin are mentioned in CX 47, 48, 50, 52, 54, 56-64, 67-70, 72-83, 101-116, 155-158.

better." This ad and others like it (CX 109, 155, 156, 158) focus on the attributes tested as well as overall quality.

Paragraph 20 also charges that the comparative tests demonstrate Bayer's *therapeutic* superiority. This allegation is essentially identical to paragraph 10(A) of the complaint. Since we have previously determined that numerous ads describing Sterling's comparative tests represent Bayer's therapeutic superiority (*supra* pp. 8-12), there is no need to repeat that analysis here.

4. *Claims that Bayer Children's Aspirin is therapeutically superior to other children's aspirin and that this superiority has been established.*

Paragraph 10(B) of the complaint alleges that respondent represented in its advertising that Bayer Children's Aspirin is superior to other children's aspirin in terms of significant therapeutic effect. Paragraph 8(A)(2) contains the corresponding establishment charge. The ALJ found that both of these representations were made by the challenged advertisements. (F. 339-351) In this instance, we agree with respondent and can find no representation of therapeutic superiority in any of the challenged ads.

For example, CX 183 states:

> It's a fever. But you know what to do. Doctors recommend aspirin to reduce the fever of a cold and relieve the aches. And you choose Bayer Children's Aspirin because when your child is sick, it's good to know you have Bayer behind you. You and Bayer. You take extra care to keep the aspirin safely stored. Bayer takes extra care to keep the aspirin pure and fresh by making over 200 quality control tests on every group of tablets. Part of a special Bayer process. You take extra care to read the label and give the right dosage. Bayer takes extra care by blending two kinds of as-

> pirin crystals instead of one so its aspirin disintegrates smoothly and gently. Part of a special Bayer process. So when your child is sick, its good to know you have Bayer behind you.

For several reasons, this ad does not represent that Bayer is therapeutically superior. First, although the ad does indicate the Bayer manufacturing process is special, the overall impression created by the ad is not one of uniqueness. To be sure one could reasonably infer from this ad that Bayer Children's Aspirin is a good product or even that it is one of the best brands of children's aspirin available. But that characterization does not constitute a representation that Bayer Children's Aspirin is *the best* children's aspirin. In addition, a central theme of this ad is that Bayer Children's Aspirin is a well-made aspirin. Unlike ads for regular Bayer discussed above (*supra* pp. 8-12) CX 183 does not stress a comparison between Bayer Children's Aspirin and all other brands. Indeed, the tests that are mentioned are quality control tests, not comparative tests. The ad does not in any way imply that Sterling is the only manufacturer which performs such tests. Thus, without additional evidence we are unwilling to conclude that consumers would make the inferential leap from the representations in CX 183 to a representation of therapeutic superiority.[22]

Another Bayer Children's Aspirin ad cited by the ALJ is CX 167. That ad states, in part. "No one makes aspirin like Bayer. No one purifies aspirin like Bayer. No one protects aspirin like Bayer." Unlike CX 183, this ad makes a superiority claim for Bayer Children's Aspirin. Nevertheless, the message is not that Bayer Children's Aspirin

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[22] Other ads which we find do not claim superiority are CX 182, 184, 209.

is therapeutically superior but that Sterling's manufacturing process is superior. As we indicated above in connection with ads for regular Bayer aspirin, a representation of superior manufacturing quality does not necessarily imply therapeutic superiority. (*supra* pp. 11-12) In ads such as CX 167, Bayer Children's Aspirin's superiority is narrowly defined in terms of specific quality attributes. Thus, there is no representation of therapeutic superiority.[23]

Finally, the ALJ discusses CX 176. That ad opens with a mother concerned about a sick child. She consults a doctor, "she keeps the patient quiet and she gives her children's aspirin. . . . She chooses orange-flavored Bayer Aspirin for children because she knows Bayer makes the best children's aspirin." Although this ad does state that Bayer makes the best children's aspirin, the reference to "best" constitutes puffing. The tone is homey, familiar and secure. In this context, "best" implies only that Bayer Children's Aspirin is a dependable product that a parent can feel secure in giving to a sick child.[24]

5. *Claims that Vanquish is a superior pain reliever and that that superiority has been established.*

Paragraphs 12(B)(1) and 12(C) of the complaint allege that respondent represented in its advertisements that Vanquish is a superior pain reliever to aspirin, buffered aspirin and the largest selling "extra strength" tablet. Paragraphs 8(B)(1) and 8(C) allege this superiority has been established. The ALJ found Sterling had represented that Vanquish was a superior pain reliever to aspirin, buffered aspirin and to the largest selling "extra strength"

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[23] Other ads representing pharmaceutical superiority only are CX 175, 185, 188, 196, 197, 205.

[24] Other ads in which "best" constitutes puffing are CX 168-170, 176-181, 194, 195, 198, 201-203.

tablet. We agree with this finding, although we find that some of the ads cited by the ALJ did not make the challenged representations. We also disagree with the ALJ's finding that the ads make establishment claims.

Vanquish is represented as a superior pain reliever to aspirin in CX 224 and 226. CX 224 states:

> Vanquish is different. It gives you the proven effectiveness of aspirin in this tablet, plus extra medications in these. . . . Vanquish is the only leading pain reliever you can buy that combines the extra strength of three medications with two gentle buffers.

The point of this ad is that Vanquish starts with aspirin and adds extra medication. Consumers could reasonably assume that the purpose of this extra medication is to provide "extra strength"—*i.e.*, extra pain relief. As the court noted in *American Home Products* v. *F.T.C.*:

> Not only credulous purchasers are apt to conflate the idea of more pain reliever with that of more pain relief, but as the Commission explains in its brief, even rational and careful consumers will be apt to place such an interpretation on the advertisements. "If the presence of more pain reliever in a product did not result in greater pain relief (as may well be true of Anacin), disclosure of the extra amount could be a clear liability since consumers would logically expect that it contributed to an increased price." 695 F.2d at 696.

Another ad, CX 226, represents that Vanquish is a superior pain reliever because it has more ingredients than aspirin. In this ad, a man states that he wants more than buffered aspirin for his headache and the announcer notes that Vanquish has added extra medication to buffered aspirin. This clearly implies that Vanquish is a superior pain

reliever to aspirin (and to buffered aspirin). CX 245 and 251 also make this implication. Both of these ads state that Vanquish has extra strength which the "leading buffered product" lacks. Ten other ads represent that Vanquish is superior to the largest selling extra-strength tablet.[25] CX 261 is typical of these ads and it states, "Vanquish contains more pain relievers than the largest selling extra-strength tablet."

Respondent argues that Vanquish was introduced in 1966 as a defensive measure to protect Sterling's share of the OTC analgesics market which was being steadily eroded by other "extra-strength" products. It contends that the Vanquish ads were designed not to represent that Vanquish was therapeutically superior but to describe the product to consumers who would otherwise purchase a competitor's "extra-strength" product. Although we appreciate that the market for OTC analgesics is highly competitive, it is important that advertisers not compete with false or deceptive advertisements. An advertiser must still be able to substantiate any claims it makes in attempting to compete.

The complaint also alleges, and the ALJ found, that Sterling made establishment claims regarding Vanquish's superiority over aspirin, buffered aspirin, and the largest selling "extra-strength" tablet. He found that the representation of establishment was made by the use of the phrase "medically-proven ingredients" in CX 254 and the phrase, "the proven effectiveness of aspirin" in CX 224. Also, he found that the mortar and pestle used in several of the ads (CX 224, 226) were "chemist's instruments" which help convey the impression that superiority is predicated upon scientific fact.

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[25] The ten ads are CX 252, 255, 256, 258-264.

We are unable to agree that any ad represents Vanquish's superiority has been established. Although the phrase "medically-proven ingredients" might imply scientific testing, the phrase is used only in one ad and that ad does not compare Vanquish with any other product. Similarly, CX 234 states that aspirin has been proven effective but does not indicate or imply that anything has been proven regarding Vanquish. Finally, the mortar and pestle in CX 224 and 226 do not, in the context of those ads, appear to be chemist's instruments. Instead, they are used to demonstrate that Vanquish is a combination of several ingredients. Although in other instances a mortar and pestle might conceivably convey establishment connotations, they do not do so here.

6. *Claims that Vanquish will cause less stomach upset than other OTC analgesics and that this representation has been established.*

Complaint paragraph 12(B)(2) alleges that respondent represented that because Vanquish contains "gentle buffers"[26] it would cause less stomach upset than any OTC analgesic not containing buffers. Paragraph 8(B)(2) alleges that respondent represented that Vanquish's superior freedom from side effects had been established. The ALJ found respondent had represented Vanquish causes less stomach upset because it is buffered and we agree.

For example, CX 245 discusses the plight of Tuesdee Testa, "a successful female jockey" who "can't afford a headache." The ad observes that "she wants more than just extra strength, she wants gentle action." After several scenes of Ms. Testa in action, the ad comments, "Look—this leading extra-strength pain reliever has no

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[26] The "gentle buffers" mentioned in the Vanquish advertising are two antacids, aluminum hydroxide and magnesium hydroxide.

buffers. . . . Vanquish—it gives you extra strength and gentle buffers. Vanquish—all the strength you need for your headache pain, yet gentle enough to your system." This ad implies that Vanquish is gentle because it has buffers and that a product lacking buffers will be less gentle to the system. Respondent argues that it was merely attempting to inform consumers that Vanquish is a multi-ingredient product. However, the ad clearly does more than that. It represents that the buffers in Vanquish make it a product that is less likely to cause stomach upset.[27]

Most of the challenged Vanquish ads promote it as "the only leading pain reliever you can buy that combines the extra-strength of three medications with two gentle buffers," (CX 224) or contain statements such as, "Vanquish is different. It gives you the well-known pain reliever in this tablet, plus extra medication in this tablet and this tablet, and buffers as in this one. Three headache relievers and two gentle buffers. . . ." (CX 241) Statements such as these imply that Vanquish will produce less stomach upset than an unbuffered analgesic. After all, why else would respondent advertise that Vanquish has buffers and some other products do not? Why else would it refer to the buffers as "gentle"? The natural inference from such advertisements is that Vanquish is "gentler" or causes less stomach upset.[28] Indeed, even respondent's expert, Dr. Miles, appears to concede that consumers may draw inferences from the mention of an ingredient in an ad for a product. (Tr. 9492-93.

However, we disagree with the ALJ's finding that the challenged ads represent that Vanquish's superior freedom

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[27] Other ads disclosing the presence of buffers in Vanquish and containing the statement that Vanquish is gentle to the system are CX 246, 247, 251.

[28] Ads which promote Vanquish as a product containing gentle buffers are CX 224, 226, 235, 236, 241-247, 250-256, 258-264.

from side effects has been established. As we stated above consumers would not infer that claims in an advertisement had been established merely because the ad shows a hand using a mortar and pestle to grind tablets. And once again, we disagree with the ALJ's conclusion that every claim of comparative superiority impliedly represents that the superiority has been established. Thus, we find that respondent represented that the presence of buffers in Vanquish causes it to produce less stomach upset than analgesics not containing buffers. However, the ads do not represent that this claim has been established.

7. *Claims that Cope is more effective than other analgesics and that this representation has been established.*

Paragraph 12(A) of the complaint alleges that Sterling's ads represent that Cope is more effective for the relief of nervous tension headache than any other OTC analgesic. Paragraph 8(A)(3) alleges that respondent represented that this claim has been established.[29] The ALJ found that all of these claims had been made, and we agree.

CX 272 is typical of the ads for Cope. It states:

> Important studies made at the world's leading headache clinic show that for relief of severe nervous tension headaches a combination of a pain reliever and a sedative provides greater relief than either medication alone. Of all leading remedies you can buy for ordinary nervous tension headaches, only Cope combines a gentle relaxer with a powerful pain reliever for really effective relief.

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[29] Paragraph 18 alleges that respondent's ads represent that tests or studies prove this superior efficacy. This is the same allegation contained in paragraph 8(A)(3). (*See supra* pp. 14-15)

The clear and direct message of this ad is that Cope is superior for the relief of nervous tension headache to any other analgesic[30] because of the formulation which it alone has. The importance of this formulation is emphasized by the reference to tests in the ad.[31] Respondent again argues that the Cope ads were merely a description of Cope's ingredients designed to introduce the product to the market. (R.A.B. p. 88) However, these ads plainly go further and describe the purpose of Cope's formulation and inform consumers that because of this formulation, Cope gives more effective relief.

This same ad also represents that Cope's superiority has been shown by studies. Read literally, the ad claims studies have demonstrated that a combination of an analgesic and sedative provides greater relief for *severe* nervous tension headache and that Cope with a similar formula provides relief for *ordinary* nervous tension headaches. Given this juxtaposition, it seems reasonable for consumers to infer that if tests show that a combination of sedative and analgesic provides more effective relief for severe nervous tension headache, these results would also support the conclusion that the Cope formula provides more effective relief for ordinary nervous tension headaches. Indeed, this inference is almost inescapable.[32]

There are numerous other indicia of establishment in the ad. It mentions "important studies made at the world's

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[30] The Cope ads actually compare Cope to the "leading remedies." Consumers could reasonably assume that a product which is superior to the leading remedies is superior to all remedies.

[31] Other ads which imply that Cope is superior for the relief of nervous tension headache to any other OTC analgesic are CX 273-276, 283, 287, 292-294.

[32] Other ads which imply that Cope's superior efficacy for the relief of nervous tension has been proven by tests or studies are CX 283, 287.

leading headache clinic," the announcer is holding what appears to be a copy of a report, and he is standing in a room lined with ponderous books. The words and the visual images of this ad imply that the basic message of the ad (Cope's superiority) has been established.[33]

B. Required Substantiation for Establishment Claims

As our analysis of the challenged advertising has shown, Sterling has represented that it is established that Bayer is therapeutically superior to any other aspirin and that it is established that Cope is more effective for the relief of nervous tension headache than any other nonprescription internal analgesic. Paragraph 28 of the complaint alleges that the truth of these claims, in fact, has not been established, and that the establishment claims are, therefore, false. The ALJ agreed. It was his determination that well-controlled clinical studies are necessary to establish an analgesic's comparative superiority, and that Sterling did not possess that sort of evidence.

Sterling has appealed the ALJ's conclusion. First, it argues that the ALJ's approach conflicts with the reasonable basis theory enuciated in *Pfizer* in that *Pfizer* precludes finding a violation based simply on a conflict in scientific opinion. (R.A.B. 20-21) Second, Sterling contends that the establishment (and substantial question) theory has improperly shifted to it the burden of proof. (R.A.B. pp. 21-22) Third, it argues that the ALJ required it to possess substantiation "more extreme than the level of certitude required by Congress and the Food and Drug Administration for the marketing of drugs." (R.A.B. p. 22) Finally, respondent argues that the First Amendment "precludes the proscription or restriction of commercial speech in areas of good faith differences of opinion."

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[33] Other ads making an establishment claim are CX 283 and 287.

(R.A.B. p. 23) We disagree with all of respondent's arguments for the reasons set forth below. We further hold that it did not establish the superiority of either Bayer or Cope.

As we explained in *Bristol-Myers*, the establishment theory is not a new theory of advertising substantiation. Slip op. at 18-19 [102 F.T.C. at 331-332]. It is based on the straightforward notion that when an advertiser represents in its ads that there is a particular level of support for a claim, the absence of that support makes the claim false. Therefore, the inquiry contemplated by *Pfizer* for reasonable basis claims does not conflict with the more narrowly focused inquiry involved where representations are made that a claim has been established or scientifically proven. Indeed, as we noted in *Bristol-Myers* (*Id.* at 18-19 [102 F.T.C. at 331-332]), a similar approach has been used in a number of post-*Pfizer* substantiation cases.

Respondent's argument that the burden of proof has been shifted to it is also incorrect. The complaint alleges that the establishment claims made by Sterling's ads are false. It is complaint counsels' burden to prove the falsity of those claims by proving that the claims have not been established.

Respondent further claims that it is being required to produce an excessive level of support for its claims. It bases this argument upon the Committee Report accompanying the 1962 amendments to the Food, Drug, and Cosmetics Act which noted that substantial evidence of efficacy is necessary before a drug can be marketed. However, that Report also recognized that there will usually be differences of opinion among scientists regarding the drug. S. Rep. No. 1744, 87th Cong. 2d Sess. part 2 at 6 (1962). We do not prevent respondent from advertising its products when such differences of opinion exist, provided, of course, that it does not represent that the position support-

ing its products has been scientifically established. To support its establishment claims, we require respondent to have supporting evidence of the type and quantity that is acceptable to the scientific community.

Respondent's constitutional argument also must fail. As respondent has noted in its brief (R.A.B. p. 23), the Supreme Court has indicated that regulation of false, misleading or deceptive advertising is not barred by the First Amendment. *Bates* v. *State Bar of Arizona*, 433 U.S. 350, 383 (1977); *Virginia State Board of Pharmacy* v. *Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976). To the extent that respondent claims in its ads that its products' superiority has been established when in fact it has not, the ads are false. There is, therefore, no constitutional impediment to the regulation of respondent's establishment claims.

1. *Establishment of Bayer's therapeutic superiority.*

A substantial portion of the briefs in this case is devoted to a discussion of the type of evidence necessary to establish the therapeutic superiority of one brand of aspirin over others. Sterling argues at great length that comparative superiority can be demonstrated without the use of well-controlled clinical tests.[34] (R.A.B. pp. 24-42) In support of Bayer's therapeutic superiority, Sterling has presented a substantial amount of nonclinical evidence, in-

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[34] In a well-controlled clinical test, drugs are tested on real patients having actual symptoms. It is not disputed in this case that the elements of a well-controlled clinical test are the use of an appropriate pain model, replication of results, experienced unbiased investigator and adequately trained personnel, a written protocol, double-blinding, use of a placebo control, use of appropriate predetermined analytical techniques, and statistical and clinical significance of the results. (F. 417) *See Bristol-Myers*, slip op. at 24-27 [102 F.T.C. at 335-339].

cluding studies comparing impurities in aspirin tablets and evidence regarding the manufacturing of Bayer. Complaint counsel argue that only well-controlled clinical studies can demonstrate the superiority of one brand of aspirin over another. The ALJ agreed with complaint counsel (F. 416) and determined that it has not been established that Bayer is superior to any other aspirin in terms of pain relief and freedom from side effects. (F. 474, 489)

The record contains the testimony of several expert witnesses who testified regarding the type and amount of evidence necessary to establish the comparative superiority of one brand of aspirin over others. Based upon our analysis of that testimony, we conclude that at the present time, the relevant scientific community would not regard superiority as established unless supported by the results of well-controlled clinical tests. The record also shows that the only clinical study in the record comparing Bayer with another brand of aspirin (RX 450) does not show any clinically significant difference between Bayer and the other brand tested.

Numerous experts testified for respondent in this case regarding the type of evidence necessary to establish comparative superiority. However, only two of the experts, Drs. Alvan Feinstein and William Fields were qualified as experts in the area of camparative testing of analgesics (F. 110, 115) and the record makes it clear that Dr. Fields had no experience in the testing of mild analgesics (such as the ones involved in this case) (Tr. 16573). Two of Sterling's other experts, Drs. Banker and Rhodes, were qualified only in the formulation and processing of drugs, and neither had any experience with well-controlled tests involving subjective response methodology. (Banker, Tr. 12872; Rhodes, Tr. 11095) Dr. Scoville was qualified only in FDA practices and procedures (F. 134), and he testified regarding the requirements of FDA regulations. The other two doctors who testified on behalf of respondent

were Sterling employees who were not qualified as experts in any particular field (Drs. Tainter and Trout; F. 159, 162). Four experts testified for complaint counsel, two of whom, Drs. DeKornfeld and Moertel, were experts in the testing of analgesics (F. 34, 54). The third expert, Dr. Grossman, was qualified as an expert in the field of gastroenterology and aspirin side effects (F. 40) and the fourth expert, Dr. Miller, was qualified as an expert in the formulation and pharmaceutical analysis of drugs. (F. 49).

Although all of these experts have experience with analgesics the record makes it clear that some of them are not experienced in comparing analgesics for the purpose of evaluating relative efficacy. For example, respondent's expert, Dr. Banker, conducted tests of analgesics for the purpose of comparing drug delivery systems[35] (Banker, Tr. 12870), and Dr. Rhodes' tests compared features of drug manufacture such as compaction pressures (Rhodes, Tr. 11084). Neither tested comparative efficacy. Complaint counsel's experts Drs. Grossman and Miller were also not experienced in comparing analgesic efficacy. It is the testimony of experts with experience in the testing of comparative analgesic efficacy that must be given the greatest weight in determining the type of evidence necessary to establish the superiority of one brand of aspirin over others. That testimony (including testimony of respondents' witnesses Drs. Feinstein and Fields) provides strong evidence supporting the conclusion that experts will not regard superiority as established unless that conclusion is supported by clinical evidence.

The need for clinical tests to establish comparative superiority was clearly stated by Dr. DeKornfeld:

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[35] A "drug delivery system" is the form given to a dose of a drug. Examples of three delivery systems used for aspirin are tablets, capsules, and effervescent powder.

> A claim of comparative superiority, I feel quite strongly that a minimum of two carefully controlled clinical comparisons, both showing statistical significance in favor of one of the two compared drugs, is essential to establish the claim of clinical superiority. . . . [M]ost people working in this area will accept two studies showing the same thing done under appropriate circumstances as establishing a claim. If the studies are lacking or if they are controversial, it would not be established. (Tr. 8388, 8391)

Dr. Moertel expressed the same idea. Speaking of clinical testing, he said "it's the only way we know to properly establish therapeutic superiority. . . ." (Tr. 6255-56) Even respondent's expert Dr. Feinstein indicated that clinical tests provided the best evidence regarding patients' subjective responses. (Feinstein, Tr. 16413)

The experts also explained why clinical tests were necessary. There is general agreement among all the experts that no direct correlation has been demonstrated between the amount of aspirin appearing in the bloodstream at any time and the onset, intensity or duration of relief afforded by the aspirin. (Moertel, Tr. 6291; DeKornfeld, Tr. 8409; Banker, Tr. 12940; Feinstein, Tr. 16482; Danhof, Tr. 17269). Therefore, studies that examine the amount of drug in the bloodstream are not reliable for comparing analgesic performance of various brands of aspirin. Consumers' perceptions are not adequate because consumers cannot evaluate for themselves the efficacy of drugs. (DeKornfeld, Tr. 8421) The reason for this is that consumers' expectations regarding drug performance play a powerful role in influencing the response to drugs. (Feinstein, Tr. 16289) Indeed, this "placebo effect" may produce pain relief in 40-50% of the subjects in controlled tests who receive pharmacologically neutral substances. (Feinstein, Tr. 16322) Finally, the pain for which aspirin is taken is

normally self-limiting—it will disappear regardless of what drug is taken. Thus, for these reasons, it is necessary to conduct well-controlled clinical studies in order to establish the superiority of a given brand of aspirin.

Respondent argues that although clinical tests are necessary when comparing different drugs, experts would not use controlled clinical trials to compare different formulations of the same drug. In support of this, respondent cites testimony of both Drs. Feinstein and Fields. Sterling also contends that no expert would ever recommend using a controlled clinical trial to compare different formulations of the same drug because that would be akin to using a jet airplane to cross the street—"theoretically possible, but hardly the most efficient or sensible way to travel." (R.A.B. pp. 25-27) For this reason, respondent contends that the pharmaceutical evidence it has presented (evidence regarding rates of dissolution, etc.) can establish Bayer's therapeutic superiority. Nevertheless, the expert testimony in this case shows that at this time the consensus of experts would require clinical tests to establish the comparative superiority of any mild analgesic, even to substantiate the superiority of one brand of aspirin over another.

The reason that nonclinical evidence (such as a blood level study) is inadequate to establish comparative superiority was explained by Dr. Moertel:

> We simply do not know at this point in time what value, if any, blood level studies have in determining comparative efficacy of mild analgesics because the studies to determine the correlation between blood levels and therapeutic effectiveness have simply not been conducted. . . . [R]ight now we do not know whether, for example, a high quick peak is good or bad in getting the most ideal therapeutic effect from salicylates because these studies have never been conducted. (Tr. 6291-92)

Dr. DeKornfeld held the same belief and stated, "I don't believe that blood levels can be directly translated at any time into establishing clinical effectiveness, unless clinical effectiveness is also measured independently." (Tr. 8409) He also stated that there is "very little, if any" relation between either the product formulation or pharmaceutical quality (size, shape, manufacturing process, presence of substances other than active ingredients) and the therapeutic superiority of any mild analgesic which meets the requirements that permit it to be marketed in this country. (Tr. 8414-15) Dr. DeKornfeld gave his opinion that the 223 Study (CX 448), a study which compared Bayer with 220 other brands of aspirin, could not be used to draw any conclusion regarding the therapeutic superiority of Bayer because it compared only physical and chemical characteristics and differences in those characteristics were not likely to have an impact on clinical effectiveness. (Tr. 8415-16)

An analysis of the testimony of respondent's experts shows that they, too, recognized the value of and need for well-controlled clinical tests. Dr. Feinstein agreed that the amount of a drug present in the blood is not well correlated with clinical analgesia. (Tr. 16413) He also conceded that there was not a high correlation between comparisons of pharmaceutical characteristics and clinical analgesia (Tr. 16415). and that in the absence of clinical trials he would have no way of saying that one drug was better than another (Tr. 16417). He did indicate that in some instances doctors must choose between two drugs (or between two brands of the same drug) and that in making that sort of decision a doctor will use whatever evidence is available to make that choice even though the evidence might not demonstrate therapeutic superiority. (Tr. 16425-27) However. all that the doctor could then feel confident of would be that the chosen drug was equal to the one not selected. Whether or not it was superior could only be determined with clinical evidence. (Tr. 16427)

The other expert with experience in testing who testified for respondent was Dr. Fields. Respondent cites his testimony in support of the proposition that clinical tests are not necessary when comparing two formulations of the same drug. (R.A.B. p. 27) However, Dr. Fields has no experience in the testing of mild analgesics and his testimony cited by respondent related to a study in which he participated that measured aspirin's effectiveness in preventing clotting and lowering the risk of stroke. Prior to conducting this study, a brand of aspirin had to be selected to administer to participants. Based upon nonclinical evidence (including the 223 Study, CX 448) Bayer was selected. Dr. Field's testimony makes it clear that the considerations of the scientists conducting the study were peculiar to the study. For example, they were concerned about factors which might tend to prevent double blinding and about whether the manufacturing process would encourage the decomposition necessary to prevent coagulation. (Fields, Tr. 16590, 16596) Although these considerations might be important in selecting an aspirin to test on potential stroke victims, they are not relevant to establishing the therapeutic superiority claimed by Sterling for Bayer.

Sterling also attempts to rely for support on several scientific articles which it contends indicate that experts do not require clinical tests when comparing two formulations of the same drug. (R.A.B. p. 27) But respondent's own expert, Dr. Feinstein, admitted that both of the articles cited by respondent were generally quite positive about the importance of well-controlled clinical trials and that the point of those articles was that clinical trials must be done carefully. (Tr. 16472-73)

The evidence in this case also shows that in the past Sterling demanded that its competitors rely on clinical studies to support their comparative claims. In 1970, in response to advertisements by Bristol-Myers claiming su-

periority for Excedrin, Sterling's advertising agency wrote on Sterling's behalf to the television network and argued that such superiority claims should not be made unless substantiated by well-controlled clinical tests. (CX 347C-E) Although it is true that Excedrin has a different formula than aspirin, Sterling requested that the same clinical test standard be imposed on other marketers of analgesics who claim superiority over aspirin for any analgesic differing in any way from the standard aspirin tablet. This request was made again in 1974 by Dr. Monroe Trout, the Senior Vice President and Director of Medical Affairs for Sterling. In an appearance before the FDA's OTC Analgesics Panel, he suggested, ". . . that OTC analgesics products containing aspirin, *with or without additional ingredients*" disclose on their labels that the product is not superior to two 5-grain aspirin tablets "unless the superiority claimed or implied by such variance is adequately established by well-controlled studies of pain relief, anti-pyresis, anti-inflammatory or side effects." (CX 456M; emphasis added) Dr. Trout made clear in his statement that the same clinical testing requirement should be imposed upon a manufacturer claiming superiority for an analgesic that was merely a larger-than-normal dose of aspirin. (CX 456M) Thus, Sterling would have required its competitors to perform clinical tests to establish the superiority of one analgesic containing only aspirin over another analgesic containing only (albeit a lesser amount of) aspirin.

Respondent objects to these references to its prior statements and contends that the ALJ has used them to estop Sterling from asserting a different position in this case. (R.A.B. p. 31) We do not believe that statements made by Sterling in the past prevent it from expressing different views in this case. However, Sterling's prior statements do provide evidence of the fact that scientists involved in the manufacture of analgesics require well-controlled clinical studies to establish superiority. These statements also

show that Sterling was aware of the significance of clinical testing. Thus, we find that Sterling's prior statements are relevant and probative of the need for clinical tests to establish Bayer's superiority.

Respondent argues that it would be inconsistent with FDA policy to hold that nonclinical evidence does not constitute a reasonable basis for its claims. Further, it argues that in some instances the FDA will permit a drug to be marketed based solely upon pharmaceutical studies. Respondent has cited several examples of drugs which were qualified by the FDA as safe and effective even though no clinical studies were submitted. (R.A.B. pp. 37-42) It is true that the FDA would permit some internal analgesics to be marketed without any clinical testing. (45 FR 77807-08, Nov. 24, 1980) However, these are analgesics whose ingredients are identical to some other drug on the market which has already been proven safe and effective with clinical studies. If it can be shown that the new drug ("generic") is absorbed into the body at basically the same rate and to the same extent as a drug already on the market, the new drug will be assumed equally safe and effective as the drug already on the market. Differences in the rate or extent of absorption are regarded as significant only if they "would result in therapeutic failure or hazard to the patient." 42 FR 1626, January 7, 1977.[36] Thus, this nonclinical evidence is only used by the FDA to support a conclusion that drugs are *equivalent*, not that one is superior to another. Indeed, the FDA Commissioner expressed the belief that if two drugs are manufactured in compliance with good manufacturing practice, if they contain identical amounts of the same active ingredients

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[36] *See U.S. v. Generix Drug Corp.*, 51 L.W. 4282 (1983), which restricts the number of generic drugs that can be marketed without new drug applications.

and if they do not present any problems regarding rate or extent of absorption, then it is reasonable to assume that the drugs are of equal efficacy. 42 FR 1625, January 7, 1977. This statement basically echoes the comment of Dr. Feinstein that nonclinical data could lead to a conclusion that two brands of aspirin are at least equally effective. (Tr. 16427)

Although the F.D.A. has never directly considered superiority claims for aspirin, it did consider a somewhat analogous issue. The F.D.A. OTC Analgesics panel was presented with nonclinical evidence regarding buffered aspirin which showed that it was absorbed into the bloodstream more rapidly than unbuffered aspirin. (This is similar to the blood level data submitted in this case by Sterling to justify its claims of Bayer's superiority.) Despite this evidence, the panel stated that no conclusion could be drawn regarding whether buffered aspirin provides more rapid relief, greater relief or more prolonged relief than unbuffered aspirin. 42 FR 35470, July 8, 1977. Thus, the FDA panel believed that blood level data could not be used to determine the comparative superiority of buffered aspirin and that controlled clinical studies were necessary to support claims of superiority. Therefore, our determination that two well-controlled clinical studies would presently be required by experts to establish Bayer's superiority over other brands of aspirin is in no way inconsistent with FDA policy or regulations.

Finally, respondent argues that it would not be feasible to conduct a well-controlled clinical study comparing Bayer with all other brands of aspirin because there are more than 200 other brands and such a test would be prohibitively expensive. (R.A.B. pp. 27-28) It also argues that it would not be ethical to conduct such a clinical trial because it would not provide a clear benefit compared to the risk of the study. (R.A.B. p. 34) However, Dr. Feinstein's testimony indicates that it would not be necessary to test all

brands of aspirin in a well-controlled clinical trial in order to establish therapeutic superiority. Pharmaceutical tests could be conducted of all brands of aspirin (as Sterling has already done). Then a clinical trial could be performed on two or three of the brands in order to demonstrate whether pharmaceutical differences correlate with therapeutic differences. This sort of scheme could clinically prove superiority and would be feasible. (Feinstein, Tr. 16462-63) Dr. Feinstein also felt that this sort of testing scheme would overcome any ethical barriers that might block a large-scale clinical study of analgesics. (Feinstein, Tr. 16462)

Thus, it is the consensus of the experts with experience in comparing analgesic efficacy who testified in this proceeding that at this time well-controlled clinical tests are necessary to establish the comparative superiority of one brand of aspirin over others. We emphasize that we are not attempting to decree what constitutes scientific establishment because this standard may change with time. Indeed, we recognize in this case, as we recognized in *Bristol-Myers,* slip op. at 69 [102 F.T.C. at 373], that relevant experts might, in some instances, regard a proposition as established even if the clinical tests do not meet all of the criteria set out above. But, as we discuss below, the substantiation possessed by Sterling was plainly inadequate to substantiate the claims it made regarding Bayer's superiority.

The record in this case does contain the results of one well-controlled clinical study comparing Bayer with other analgesics. That is the Lasagna-DeKornfeld Study conducted by Drs. Louis Lasagna and Thomas DeKornfeld (who testified for complaint counsel in this proceeding).[37]

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[37] This study was undertaken in 1960 at the request of the F.T.C. in order to evaluate superiority claims made in advertising for each of the tested analgesics. (DeKornfeld, Tr. 8332)

Its results were published in 1962 in the *Journal of the American Medical Association*. The study was randomized, placebo controlled, and double-blinded. According to Dr. Robert John who was medical director of respondent's Glenbrook Laboratory from 1971-1974 (and who testified for complaint counsel), respondent was aware of the study (John, Tr. 5546-47). Furthermore, respondent relied on the study to support advertising claims made to the public and to support complaints to the FTC concerning competitors' advertising. (Admissions 713, 714 in CX 678)

The Lasagna-DeKornfeld Study tested the analgesic performance of five OTC analgesics. Two of the five analgesics tested, Bayer and St. Joseph's, were plain 5-grain aspirins. The other three, Anacin, Excedrin and Bufferin, were combination products. Doses were administered to test subjects suffering pain and then the amount of pain relief received by each subject was recorded at seven time intervals after administration. After examining the results of the study, it was the conclusion of respondent's expert Dr. Feinstein that the study did not show any difference in therapeutic effectiveness between any of the products tested. (Tr. 16397) Indeed, Dr. Feinstein agreed that the Lasagna-DeKornfeld Study did not indicate any clinically important difference between Bayer and St. Joseph's aspirin, and when asked which of the two brands he would choose, Dr. Feinstein indicated that he would select the cheaper. (Tr. 16438) The Lasagna-DeKornfeld Study is significant because it shows that it is possible to conduct a well-controlled clinical study comparing different brands of aspirin. It is also the only such study introduced in this case and it failed to demonstrate a clinically significant difference between the brands tested. Thus, it clearly has not been established that Bayer is therapeutically superior to all other brands of aspirin.

2. Establishment of Cope's superiority.

The other establishment claim made by respondent was that Cope is more effective than any other nonprescription internal analgesic for the relief of nervous tension headaches. Respondent does not dispute that well-controlled clinical tests are necessary to establish the therapeutic superiority of one drug over a different drug. In fact, in its brief, respondent quotes a statement from its expert, Dr. Feinstein, that pharmacokinetic information cannot be used to compare two different drugs. (R.A.B. p. 26) However, the clinical evidence that respondent has submitted is inadequate to establish that Cope is superior to other OTC internal analgesics for the relief of nervous tension headache.

First, respondent has submitted evidence regarding the contents of a Cope tablet.[38] Sterling contends that the larger amount of aspirin in Cope (842 mg. compared to 650 mg. in a standard dose) necessarily provides increased analgesia. None of the studies submitted by respondent actually compare Cope's dose of aspirin with a standard dose. Furthermore, the Parkhouse Study discussed by respondent's witness, Dr. George Goldstein, demonstrated no statistically significant difference between aspirin dosages of 600 mg. and 1200 mg. (Tr. 15614) This finding is in accord with the conclusion of the FDA's OTC analgesics Panel which stated that:

> [T]here are no data available to show that multiple dosages greater than 650 mg. will provide any greater clinical benefit for analgesic and antipyretic effects. 42 FR 35364, July 8, 1977.

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[38] A Cope tablet contains 421 mg. of aspirin, 32 mg. of caffeine, 50 mg. of magnesium hydroxide, 25 mg. of aluminum hydroxide gel, and 12.5 mg. of methapyrilene fumarate. (F. 799)

Thus, the mere fact that Cope has a greater than normal amount of aspirin does not establish its superiority.

Respondent has also submitted four clinical studies conducted on Cope. Only two of those compared Cope with other analgesics. (The other two compared different versions of Cope's formula with a placebo only and therefore cannot establish Cope's superiority.) Of the two remaining studies, the first compared Cope with aspirin. In this study the formulation of Cope differed slightly from the marketed version. (Moertel, Tr. 6342) The study does not employ a placebo control so it is impossible to evaluate the sensitivity of the testing procedure. (Moertel, Tr. 6344) In addition, in the course of performing the study, the investigators changed their method of statistical analysis when they discovered that as originally designed their study would not demonstrate any difference between Cope and aspirin. Complaint counsel's witness, Dr. Moertel, an expert in analgesic testing, referred to this as "a gross and obvious example of statistical manipulation and this is simply not acceptable scientific methodology." (Tr. 6345-46) Dr. Moertel noted that by changing methods of analysis, the investigators were able to generate results for some parameters that showed Cope to be superior to aspirin. (Tr. 6348) However, because of the numerous flaws in the study, Dr. Moertel concluded that the study did not provide any evidence to establish that Cope is superior to aspirin and "certainly offers no evidence that it is superior to all other analgesics." (Tr. 6348)

Dr. Moertel also reviewed the other clinical study, which compared Cope with Anacin, and it was his conclusion that "this study offers very strong evidence that there is no difference at all between Cope and Anacin, and offers no evidence of any superiority of Cope over any other marketed analgesic." (Tr. 6349) He based this opinion upon the fact that this study contained the same flaws as the study comparing Cope with aspirin (different formulation tested, no placebo control, shift in analytical tech-

niques). (Tr. 6349-50) Also, in this study, there was no significant difference for any of the parameters analyzed. (Tr. 6350)

Our examination of the ads in this case show that respondent made claims of established superiority for Bayer and for Cope. The evidence shows that, in fact, relevant experts would not regard either product as having been established as superior. Therefore, respondent's advertised claims are false.

3. *Bayer's superior pharmaceutical quality.*

In addition to the claims of established superior efficacy which Sterling made for Bayer and Cope, Sterling also represented that it had tested Bayer against 220 other brands of aspirin and that this test demonstrated that Bayer was superior to the other brands with respect to quality, purity, freshness, stability, and speed of disintegration. Although grouped apart from the other establishment claims, these claims, alleged in paragraphs 20 and 21 of the complaint are, in fact, akin to establishment claims because the advertisements claim that Bayer's superior qualities were demonstrated by the test comparing it with 220 other brands. In the previous sections of this decision, we have found that experts require claims of superior efficacy to be substantiated with well-controlled clinical tests. However, Sterling contends that claims of superior manufacturing quality may be substantiated with various chemical and sensory tests.[39]

In 1968 Sterling conducted a test entitled, "Quality Comparison of Bayer Aspirin and Competitive Aspirin Prod-

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[39] As we noted above (*supra* pp. 11-12) claims of pharmaceutical (or manufacturing) quality are linked to and often imply therapeutic quality. However, if appropriately qualified, an ad may make a claim solely regarding such characteristics not directly related to therapeutic quality.

ucts of the American Market," (the "223 Study") which compared Bayer with 220 other brands of aspirin and aspirin-based analgesics. In this test, 30 different product attributes were tested by nonclinical means. Several of the attributes tested were related to purity, freshness, stability, and speed of disintegration. Sterling claims that this study substantiates its claims related to Bayer's quality. However, the ALJ concluded that this test did not demonstrate that Bayer was purer, fresher, more stable, or quicker to disintegrate than the other brands tested. Furthermore, he concluded that the test did not demonstrate that Bayer was superior in overall pharmaceutical quality to the other tested brands. From these conclusions respondent has appealed. (R.A.B. pp. 51-56)

Sterling argues that the ALJ's analysis of the 223 Study is invalid and that it is improper to examine specific pharmaceutical parameters in isolation. It contends that the 223 Study should be used only to make a judgment regarding overall pharmaceutical quality. (R.A.B. pp. 43, 56, 85-86) Although it may originally have been Sterling's intent to use the 223 Study only to reach a conclusion regarding pharmaceutical quality, its ads represent much more than that. Consumers could reasonably interpret the ads discussed above (pp. 8-14) to indicate that Bayer had been compared to 220 other brands and that the tests showed Bayer to be purest, freshest, most stable, and quickest to disintegrate.[40] Thus, it is valid to examine the individual attributes tested in the 223 Study to determine whether that evidence supports the specific claims made in the ads.

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[40] Not every ad which mentioned a tested attribute necessarily implied that Bayer was superior with respect to that attribute. In some ads, attributes were mentioned only as examples of the tests performed to demonstrate Bayer's superior overall quality. *See* CX 48.

First, a facial examination of the evidence shows that Bayer is not quicker to disintegrate than all other tested brands of aspirin. Two of the thirty tests in the 223 Study involved speed of disintegration. The results (CX 430A, B) show that all tested samples of Bayer passed both tests. But so did all tested samples of at least 22 other brands.[41] Thus, with respect to speed of disintegration, it is impossible to conclude that the 223 Study shows Bayer to be superior to all other tested brands. In addition, Sterling also had in its possession several other studies of rates of tablet disintegration which show that some other brands disintegrate as rapidly as Bayer. (F. 634, 645)

The results of the 223 Study also do not show that Bayer is purer than all other tested brands of aspirin. Expert witnesses testified that an aspirin tablet may contain a veritable alphabet soup of impurities including FSA, ASAN, ASSA, and SSA (substances whose full names are free salicylic acid, aspirin anhydride, acetylsalicylsalicylic acid, and salicylisalicylic acid; *see* Rhodes, Tr. 11159; Falliers, Tr. 13346, 13361, 13363). The 223 Study only tested for one of those impurities, FSA. Two of the thirty tests measured the level of FSA in the various brands. All of the tested samples of Bayer passed one of the FSA tests but one Bayer sample failed the second test. However, all tested samples of Parke-Davis and Safeway brands passed both of the FSA tests. Thus, the 223 Study does not show that Bayer is the purest of all brands tested.

Some Bayer ads also represented that Bayer was the most stable of all brands tested. According to the charts reporting the results of the 223 Study (CX 430A, B), five of the thirty tests measure product stability (*i.e.*, tendency to decompose). Since FSA is created when aspirin decomposes, the two tests measuring the presence of that im-

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[41] Among the brands that disintegrated as rapidly as Bayer were McKesson, Norwich, Parke-Davis, Rexall, and St. Joseph. (CX 430 A)

purity measure the extent of decomposition. Also relevant (according to the charts) are tests to determine if tablets are off-color, have acetic odor, and if the cotton wadding in the bottle has decomposed. The results of the 223 Study show that no Bayer samples had acetic odor, were off color or had decomposed wadding. However, as indicated above, the Bayer samples were unable to pass one of the tests for FSA content. The Parke-Davis sample tested passed all five tests. In addition, according to the testimony of respondent's witness, Jerome Winig, a chemist who was involved in the manufacture of Bayer aspirin for more than 40 years (I.D. pp. 50-51), acetic odor and off-white color may be caused by the manufacturing process and may not be an indication of decomposition. He testified that a test for the presence of FSA is a much more accurate measure of decomposition. (Tr. 14231, 14242) Examining test results for FSA levels, both Parke-Davis and Safeway brands performed better than Bayer. Thus, the 223 Study did not demonstrate that Bayer was the most stable brand tested.

Although Sterling's ads claimed that Bayer had been tested against 220 other brands of aspirin and been found the freshest, "freshness" does not appear to have been a product attribute specifically tested in the 223 Study. An examination of the 223 Study results shows that no test or group of tests is listed as a test of freshness. Indeed, Dr. Rhodes, respondent's expert in the formulation of drugs stated that "freshness" is not a technical term used in the industry and that it is just an imprecise "layman's term." (Tr. 11441) Nonetheless, he believed that the 223 study did test for freshness because it tested "the odor of the tablet, the amount of FSA present, the appearance, the integrity of the seal." (Tr. 11442) Dr. Rhodes stated that in his opinion the 223 Study showed Bayer to be superior. As we indicated above, there are four tests related to FSA, tablet odor and appearance. Bayer and Safeway passed three of those tests and Parke-

Davis passed all four. While one might dispute whether integrity of the seal directly relates to freshness, two of the thirty tests evaluated how well the tested products were sealed. Bayer, Safeway, and Parke-Davis each passed and failed one test. Consequently, even according to the criteria which Dr. Rhodes used to determine freshness, Bayer appears to be no fresher than at least two other brands tested in the 223 Study.

Does the 223 Study demonstrate that Bayer is superior in overall pharmaceutical quality to the other 220 brands tested? That is the final issue presented by paragraphs 20 and 21 of the complaint. Sterling argues that Bayer performed better overall than any other brand in the 30 tests that composed the 223 Study. Since Bayer samples failed only five of the 30 tests and every other brand failed more, Sterling contends the study demonstrated that Bayer is the superior quality aspirin. The ALJ did not agree. He determined that, for several reasons, the 223 Study was inadequate to demonstrate Bayer's superior quality. First, the protocol was not adequate. (F. 1164) Second, there were inadequate records of the means used to collect and handle the samples tested. (F. 1166) Third, the study failed to control for the age of samples. (F. 1168) Fourth, a Sterling employee selected the parameters to be tested. (F. 1169) Fifth, all tests, including unblinded sensory tests, were conducted by Sterling employees. (F. 1170) Sixth, Bayer samples were transported by a different means than other samples. (F. 1174) Seventh, some of the Bayer samples came from Sterling's warehouse and not from the store shelves. (F. 1175) Eighth, some minor brands were grouped together in a somewhat arbitrary fashion. (F. 1177) Ninth, there were no tests for statistical significance of demonstrated differences. (F. 1179) In addition to these methodological flaws, the ALJ noted that Bayer was not superior to all other brands in all respects tested. (F. 1179) Thus, he determined that the

223 Study was not capable of demonstrating qualitative superiority.

Respondent objects to this conclusion and argues that the ALJ's reasoning was not supported by expert testimony. It notes that Sterling's experts uniformly agreed that the 223 Study showed Bayer to be qualitatively superior but that none of complaint counsel's experts testified to flaws in the study. (R.A.B. pp. 51-56) Complaint counsel concede that none of their experts testified regarding the 223 Study but they contend that the study fails to meet standards required by relevant experts. Complaint counsel contend that these standards were derived from the expert testimony of Sterling's own witnesses. (C.An.B. p. 36)

It would, of course, be possible for complaint counsel to meet its burden of proof on this issue by showing that the 223 Study did not live up to standards set forth by respondent's experts. Thus, it is not essential that complaint counsel present testimony from their own experts on every issue. However, after considering the arguments of counsel and the testimony, it does not appear to us that complaint counsel have been able to meet their burden of proof on this issue. For example, complaint counsel quote testimony from respondent's experts to show that nonclinical tests must be subjected to statistical analysis. (C.An.B. pp. 37-38) Specifically, they cite testimony from Drs. Horner, Feinstein, Danhof, and Ranker. Yet, an examination of the testimony cited shows that in no instance does it truly apply to the 223 Study. Dr. Horner noted that in general it is important to test for statistical significance (Tr. 10850), but he did not indicate that the results of the 223 Study lacked statistical significance. Dr. Feinstein stated that in evaluating clinical studies, it is important to test for statistical significance. (Tr. 16428) But he did not indicate that the same sort of statistical analysis should be applied to the sorts of tests conducted in the 223 Study. The portion of Dr. Danhof's testimony cited by complaint

counsel discussed a study of gastric bleeding in which no statistically significant differences had been shown. (Tr. 17241-42) Dr. Danhof did not mention the 223 Study. Finally, in his testimony, Dr. Banker stated that if a study shows a large difference, a test for statistical significance may not be necessary. Only when small differences are demonstrated must they be tested for statistical significance. (Tr. 12904-05) Dr. Banker does not indicate whether the differences demonstrated in the 223 Study were large or small.

Other testimony regarding other alleged flaws cited by complaint counsel also suffers the same problem—it is not clearly related to the 223 Study. The testimony adduced by complaint counsel from respondent's experts was of a general nature. None of those experts indicated that the 223 Study was flawed or that conclusions should not be drawn from it. Thus, although the shortcomings of the 223 Study might prevent it from demonstrating Bayer's superior quality, we do not think that complaint counsel have met their burden of proof on this issue.

C. The Substantial Question Issue.

Paragraph 12 of the complaint restates four superiority claims which respondent made regarding Cope and Vanquish.[42] Paragraph 13 alleges that a substantial question as to the validity of these claims exists among experts. Then paragraph 14 charges that even in those instances in which the ads did not indicate that the claims had been

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[42] The four comparative claims are: (1) Cope is a more effective reliever of "nervous tension headache" than any other OTC internal analgesic; (2) Vanquish is a more effective pain reliever than aspirin or buffered aspirin; (3) Vanquish will result in less stomach discomfort than any unbuffered OTC internal analgesic; and (4) Vanquish is a more effective pain reliever than the largest selling "extra strength" tablet. As we discussed in part A, respondent's ads made all four of these claims.

established, the failure to disclose the existence of the substantial question rendered the ads deceptive. The ALJ found the ads deceptive and entered an order provision which would require respondent to substantiate every comparative performance or freedom from side effects claim with a type and quantity of evidence necessary to establish the claim among experts. If that degree of substantiation was lacking, the ALJ's order would require respondent to disclose in the ad the existence of a substantial question as to the claim's validity. However, as our decision in *Bristol-Myers* indicates, slip op. at 38-44 [102 F.T.C. at 348-355], we no longer endorse the substantial question theory of liability. For reasons set forth in that decision we dismiss all the allegations of paragraphs 12-14.[43]

D. Lack of a Reasonable Basis

Unlike *American Home Products* and *Bristol-Myers*, the complaint in this case alleges that for certain of its comparative performance claims, Sterling lacked a reasonable basis. Specifically, paragraph 10 of the complaint alleges that Sterling claimed Bayer is therapeutically superior to any other aspirin and that Bayer Children's Aspirin is therapeutically superior to any other children's aspirin. Paragraph 11 alleges Sterling lacked a reasonable basis for those claims. As we indicated above, our examination of the challenged advertisements in this case did not reveal

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[43] Application of the substantial question theory would require a conclusion that consumers expect the same level of support for a claim regardless of whether Sterling represents the claim has been established. Had complaint counsel presented evidence showing that consumers held such a belief—*i.e.*, that consumers believed that all superiority claims were scientifically established—then the failure to disclose the lack of evidence establishing such claims might well have been deceptive. However, as in *Bristol-Myers*, no evidence of consumer beliefs was presented here.

any ad in which Sterling represented that Bayer Children's Aspirin was therapeutically superior to other brands (*supra* pp. 15-16). Furthermore, all advertisements which represent that Bayer is therapeutically superior to other brands also represent that Bayer is therapeutically superior to other brands also represent that Bayer's superiority has been established (supra pp. 12-13).[44] For that reason, we have considered the amount of support necessary to establish these claims among members of the relevant scientific community. In determining whether respondent possessed a reasonable basis to support these very same claims, we must apply the same standard. According to *Pfizer*, one of the factors to consider in determining whether an advertiser possesses a reasonable basis to support a claim is the nature of the claim. 81 F.T.C. at 64. Since Sterling has represented in its ads that Bayer's superiority has been established, it could not have a good faith belief in the truth of that claim unless adequate evidence existed to establish Bayer's superiority. Thus, in this instance, the reasonable basis approach requires the same level of support as the establishment theory. Since we have already determined that Bayer's superiority was not established, we therefore also find that Sterling lacked a reasonable basis for this claim.

III. Tension Relief Claims

Paragrah 15 of the complaint in this case alleges that Sterling represented that Bayer, Cope and Midol relieve nervous tension, stress, fatigue and depression. Paragraph 16 charges that Sterling lacked a reasonable basis for these claims. The ALJ found that respondent made the claims

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[44] We therefore find it unnecessary to decide whether the evidence Sterling had would have been sufficient to provide a reasonable basis for an unembellished superiority claim (*i.e.*, one not representing that superiority had been scientifically established).

without a reasonable basis and he entered an appropriate order provision. We agree with respect to the claims for Cope and Midol, but disagree with respect to the claims for Bayer.

A. The Advertisements.

The ALJ cites ten ads which represent that Cope relieves tension.[45] Each of these ads presents Cope as a product especially designed to relieve nervous tension headache, and each ad indicates that Cope has an ingredient that relieves pain and an ingredient that relieves nervous tension. For example, CX 273 states:

> This is the most common headache there is, the nervous tension headache. As you can see, it's a two fold problem. Nervous tension and pain. For relief, try the two fold approach you get with Cope. Cope alone of all the leading headache remedies you can buy gives you a powerful pain reliever plus a proven relaxer. . . .

The implication of this ad is that a nervous tension headache is a combination of two problems, tension and headache. Cope is represented as having an ingredient to cure each of these problems. Thus consumers could reasonably infer that if they were tense, they could take Cope because one of Cope's ingredients is specifically intended to relieve nervous tension. The other nine ads cited by the ALJ make a similar representation.

The ALJ found that 17 ads for Midol represent that it relieves nervous tension. (F. 390) We agree with respect to 16 of those ads.[46] In all of these ads, Midol is presented as a product that relieves menstrual cramps. In addition

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[45] CX 272-276, 283, 287, 292-294.

[46] CX 296A, 297-300, 306, 306A-C, 306R, 306Z005, 306Z011, 306Z035, 306Z037, 306Z041, 306Z045, 306Z053.

to relieving cramps, each of the ads also represents that Midol can cure a number of other ills. For example, CX 296A states:

> Midol goes to work fast to help relieve a woman's discomforts. Like low backache, headache, calms jumpy nerves too. And the over all action of Midol chases the blues away.

CX 306Z035 indicates that Midol will "soothe irritability" and CX 306Z037 states that Midol contains "a special mood-brightener that gives you a real lift." In CX 306B, a woman is described as tense before she takes Midol and happy afterwards. All of these ads represent that Midol will relieve tension ("calm jumpy nerves," "soothe irritability") and most of them also portray Midol as able to relieve depression because it is a "mood brightener." Thus, respondent did represent that Midol relieves tension, depression and stress.

Finally, the ALJ determined that five advertisements for Bayer represent that it will relieve tension (CX 29, 30, 33, 141, 151). Although it is a close call, we find that complaint counsel have not met their burden of showing that any of these ads represents that Bayer will relieve tension. Typical of these ads is CX 30. It is a television ad which shows a mother on a hot summer day attempting to tend numerous noisy neighborhood children in a backyard pool. As the scene progresses, the mother becomes more fatigued and irritable. The announcer states:

> As the day wears on, "Hot Weather Headache" can make you tense, irritable, out of sorts. And that's when Bayer works wonders. . . . Take two Bayer tablets and put your feet up. In just minutes, headache's gone.

At the close of the ad, the mother appears refreshed and happy. Although this ad does mention tension and does

depict a potentially tension provoking scene, the message of the ad appears to be that the hot, hectic day gives the mother a headache and the headache, in turn, makes her tense. The ad then states that Bayer will relieve the headache. The implication is that headache relief causes the tension to disappear.

We considered a somewhat similar ad in *Bristol-Myers*. In that case, CX 53 depicted a tense confrontation between a student and a college dean. The audio portion of the ad stated that Bufferin provided relief from headache. We ruled that CX 53 did represent that the product would cure tension, but in that case we had copy tests showing that more than 50% of viewers received the impression Bufferin relieved tension. In this case, since the claim is not apparent to us from a careful examination of the ads, we are unwilling in the absence of extrinsic evidence to find that consumers infer from these ads that Bayer will relieve tension. No extrinsic evidence was presented and therefore we find that Sterling did not represent that Bayer relieves tension.

B. Evidence on Tension Relief.

Cope and Midol both contain aspirin. In addition, Cope contains buffers, caffeine and an antihistamine, methapyrilene fumarate. Midol contains (in addition to aspirin) caffeine and an antispasmodic, cinnamedrine hydrochloride. Sterling has presented no evidence indicating that caffeine, buffers or cinnamedrine hydrochloride produce any tension relieving effect and there is expert testimony confirming that none of these three ingredients relieves tension. (Rickels, Tr. 7974, 8019, 8021). Indeed, caffeine, an ingredient in both Cope and Midol is contraindicated for the relief of tension. (Rickels, Tr. 7974) However, respondent did present evidence that aspirin and methapyrilene fumarate have tension relieving properties, and it is to that evidence we now turn.

The evidence presented by Sterling regarding its tension-relief claims must be considered in light of the factors set forth in *Pfizer* for determining what constitutes a reasonable basis. The ads at issue here advise consumers to take aspirin-based analgesics for the relief of tension. If the products cannot provide that relief, then consumers may forego effective remedies and are needlessly being encouraged to consume aspirin, a drug with potentially hazardous side effects. (*see* infra p. 47) Furthermore, as with other performance claims regarding mild analgesics, it is virtually impossible for consumers to verify for themselves whether the product can relieve tension. All of these considerations are relevant to determining whether Sterling's evidence constitutes a reasonable basis for its claim.[47]

As we mentioned in *Bristol-Myers*, tension can be caused or exacerbated by headache pain. Since aspirin can relieve a headache, it could relieve or lessen the tension caused by a headache. However, respondents' ads represented that Cope and Midol could relieve tension which exists independent of headache pain. Thus, the mere fact that aspirin relieves pain does not by itself support claims that aspirin has tension-relieving properties. (Rickels, Tr. 8102-03)[48]

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[47] Sterling appears to argue (in connection with its claims for Bayer) that the Commission is precluded from anything more than a superficial determination of a scientific test's adequacy. We disagree and will, in appropriate situations, consider evidence regarding the details of scientific tests in order to determine whether the advertiser's reliance thereon was reasonable. *See Bristol-Myers*, slip op. at 32-37 [102 F.T.C. at 343-347]; *Porter & Dietsch*, 90 F.T.C. at 870-871; *Firestone*, 81 F.T.C. at 445-449.

[48] Dr. Rickels gave the following analogy to illustrate the point: A person with a bladder infection may have to urinate frequently during the night and be unable to sleep the whole night through. An antibiotic which cures the infection would permit the person to sleep the entire night but the antibiotic would not, therefore, be considered a sleeping aid.

To support its claim that aspirin can relieve tension, Sterling has relied on various studies and reports in medical literature. The first item was a 1965 study by Krumholtz and Merlis. This study was also submitted into evidence in *Bristol-Myers*, and once again, Dr. Rickels, complaint counsel's expert on psychopharmocology and tension, criticized flaws in the study, especially the failure of the authors to identify the symptoms of the test population. It is therefore possible that changes experienced by the test subjects resulted from the analgesic effects of aspirin. (Tr. 8115-16) Furthermore, the study was designed to measure aspirin's effect on depression rather than tension, and the authors recognized that additional study was necessary to test the tranquilizing action of aspirin. (Goldstein, Tr. 17977)

Much of the other evidence presented regarding aspirin related to its ability to overcome insomnia. However, sleeplessness can be caused by many factors other than tension. (L. Goldstein, Tr. 17900) Thus, a mere showing that aspirin has hypnotic (sleep-inducing) effects does not constitute a reasonable basis for tension relief claims unless it is shown that the sleeplessness was caused by tension. Sterling submitted a report of a 1959 study by Boyd, *et al.*, which reported that buffered aspirin had hypnotic effects. However, the record does not show that any of the insomniacs who participated in the study suffered from tension. Furthermore, the record shows that a substantial majority of subjects in Boyd's study were receiving other medication including barbiturates (a sleep-inducing drug). (Goldstein, Tr. 17981) Finally, Dr. Rickels noted that the study had methodological flaws. (Tr. 8178)

Sterling also submitted three reports from medical literature and a chapter from a 1969 textbook supporting aspirin's efficacy as a tension reliever. The three reports refer to potential sedative effects of aspirin, not to tension relief. (Goldstein, Tr. 17849, 17851, 17852) Thus, these reports do not make clear whether aspirin relieves sleeplessness

caused by tension or whether aspirin relieves pain thereby permitting the subject to sleep. (Goldstein, Tr. 17983-84) References to medical texts, without more, are not given much weight by scientists. Normally, they look to the underlying data and not to the text. (Rickels, Tr. 7978) Indeed, neither the textbook reference nor the three reports contain any underlying data.

Sterling additionally offered several electroencephalagram ("EEG") studies to support its tension-relief claims. However, Dr. Rickels noted that because EEG studies are not able to directly measure a drug's ability to relieve tension, they only give a preliminary indication of what a drug can do. (Rickels, Tr. 7970, 8184-85) Indeed, in some instances EEG's have indicated that a change was taking place in a subject when clinical studies have been unable to show any change. (Rickels, Tr. 8185) In addition, EEG results can be misleading because of variability among test subjects. (Goldstein, Tr. 17959-61) Respondent's witness Dr. Goldstein criticized four EEG studies submitted by Sterling (including three studies which he had conducted) based upon the failure to take variability into account. He indicated that by failing to take variability into account, he "was mixing apples and oranges and expressing their averages in terms of bananas." (Tr. 17959) The only other EEG study was conducted in 1978, long after Sterling had made the claims at issue in this case. Although the authors concluded that aspirin did improve the sleep of insomniacs, Dr. Goldstein noted that there were individual differences among the eight test subjects and that two received no benefit at all. He concluded that this was caused by the fact that the test subjects were insomniacs and there was no indication as to what the cause of each patient's insomnia was. (Tr. 17900) Finally, Dr. Goldstein conceded that the FDA would not rely solely on EEG studies to demonstrate the sedative property of a drug. (Tr. 17987)[49]

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[49] In addition to the tests and studies discussed above, Sterling

In addition to the evidence submitted by respondent, complaint counsel submitted evidence on two studies which show that aspirin does *not* relieve tension. The first was a study conducted by complaint counsel's expert Dr. Rickels in 1971 and it showed that a 500 mg. dose of aspirin (the normal dose is 650 mg.) was no more effective as a tension reliever than a placebo. (Rickels, Tr. 7951) The second study was also well-controlled, and it tested a normal dose of aspirin. It was the authors' conclusion that aspirin was not able to relieve tension. (Rickels, Tr. 8195) These studies indicate that at the time respondent was making tension relief claims for Cope and Midol, it was possible to conduct well-controlled studies measuring tension relieving capacity and that such studies showed aspirin was not a tension reliever. Furthermore, a letter from Sterling's files (CX 358) shows that as of May 1969 (prior to making most of the tension relief claims), Sterling was well aware that aspirin would not relieve tension. Thus, respondent did not have a reasonable basis for believing aspirin would relieve tension.

Methapyrilene fumarate, an ingredient in Cope, is an antihistamine (a substance which combats infection). Sterling presented a variety of evidence (but no expert testimony) regarding methapyrilene (including two clinical studies). However, none of this evidence provides a reasonable basis to substantiate the tension relief claims for Cope. First, most of the participants in the two clinical studies had headaches. (F. 938) By not separating those participants who had only tension from those who had pain, it is

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presented evidence designed to show that ingestion of aspirin increases the body's level of tryptophan, an amino acid which must be present at certain levels for sleep to begin. However, as explained above, producing sleep is not the same as reducing tension and thus, this evidence does not support tension relief claims regarding Cope and Midol.

impossible to conclude that Cope had tension relieving properties separate from its analgesic properties. (Rickels, Tr. 8007) Since the Cope ads represent that Cope can relieve this "free-floating" tension, these tests do not support those claims. The journal excerpts submitted by Sterling (F. 945) suffer from the same flaw.

Second, since methapyrilene fumarate is an antihistamine, it is also a hypnotic. However, as explained above, inducing sleep is not the same as relieving tension. Indeed, drowsiness would be undesirable, even dangerous, when produced as a side effect of a drug taken during the day. (Rickles, Tr. 8183) For that reason, eight studies submitted by Sterling demonstrating methapyrilene's sleep inducing properties do not support tension relief claims. The same is true of the bibliographic material listed in F. 946.

Finally, Sterling relied on numerous works of Dr. Arnold Friedman. Dr. George Goldstein,[50] a Sterling employee, said these articles implied that an ingredient with sedative properties is appropriate to treat tension. (Tr. 15508) However, Dr. Friedman's writings concerned the effects produced by a combination of an analgesic and a barbiturate and as Dr. Rickels, an expert in pharmacology, indicated, it would not be proper to draw any conclusions about an antihistamine (such as methapyrilene fumarate) from data regarding a drug containing a barbiturate. (Rickels, Tr. 8016)

Although respondent has presented some evidence to show that Midol will brighten a user's mood, it presented no such evidence to the FDA. In its submission, it claimed

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[50] Two Drs. Goldstein testified for respondents. Up to this point, all references have been to the testimony of Dr. Leonide Goldstein, an expert in the biological basis of human behavior (F. 121). Dr. George Goldstein was qualified as an expert only in the use of Sterling's products.

only that the ingredients in Midol would relieve menstrual pain. (George Goldstein, Tr. 15603) However, in this proceeding, respondent has claimed that the caffeine in Midol acts as a mood brightener. The claim is based in part on the testimony of Dr. George Goldstein. Dr. Tainter, another Sterling employee, disagreed and indicated that the presence of caffeine in Midol might heighten the user's pain and would, in any event, be too small a dose to affect the user's mood. (CX 417B) Also, Drs. Goodman and Gilman, who were recognized by respondent's witness Dr. George Goldstein as "among the leading lights of American pharmacology" (George Goldstein, Tr. 15590) do not list brighter mood among the effects of a therapeutic dose of caffeine (George Goldstein, Tr. 15593-94). Finally, the rest of the evidence presented by Sterling makes it appear that the amount of caffeine in Midol is too small to have any therapeutic effect. (Rickels, Tr. 7974; George Goldstein, Tr. 15587, 15592)

The evidence presented by respondent thus is inadequate to substantiate the mood altering claims it made for Cope and Midol. None of the evidence which Sterling presented regarding aspirin separates its unquestioned analgesia from any tension-relieving effect it may possess. Other evidence (such as EEG studies and the tryptophan theory) is inconclusive, especially in light of the well-controlled studies presented by complaint counsel which show that aspirin relieves tension no more effectively than a placebo, and the letter from Sterling's files showing that it knew substantiation did not exist for the claim that aspirin relieved tension. The evidence presented regarding methapyrilene fumarate is either not helpful because any tension-relieving effect Cope might produce was not isolated from Cope's analgesic effect, or of questionable relevance (*i.e.*, the studies regarding barbiturates). The evidence regarding the caffeine in Midol does not clearly show that caffeine can brighten one's mood and also seems to indicate that

under any circumstance, Midol does not contain enough caffeine to have any effect. Thus, in light of the claims made by respondent for its products, in light of the testimony, we conclude that respondent did not possess a reasonable basis for its claims that Cope and Midol can affect a user's mood.

IV. Failure To Disclose The Presence of Aspirin; Representation That Midol Contains Other Than Ordinary Aspirin

Paragraphs 23 through 25 of the complaint charge that Sterling failed to disclose in its advertising that Vanquish, Cope, and Midol contain aspirin. An examination of the challenged advertisements for these products shows that none disclose that aspirin is an ingredient. However, as we explained in *Bristol-Myers*, slip op. at 54 [102 F.T.C. at 361], we are unprepared to hold that the mere failure to disclose the presence of aspirin in advertising for aspirin-based analgesics renders that advertising materially misleading. In *Bristol-Myers*, we found that advertisements for Bufferin and Excedrin created the impression that those products did *not* contain aspirin. In light of that advertising, we held that the failure to disclose the presence of aspirin was materially misleading. In this case, there are no allegations that Sterling's advertising created the impression that Vanquish and Cope do not contain aspirin. For that reason, we find that the failure to disclose the presence of aspirin in Vanquish and Cope does not violate the FTC Act and we dismiss all charges related to Paragraphs 23 and 24. On the other hand, Paragraph 26 alleges that advertisements for Midol represented that it does not contain aspirin and caffeine. These representations would make the failure to disclose the presence of aspirin a violation of the FTC Act.

The only active ingredients in Midol are aspirin, caffeine, and an anti-spasmodic, cinnamedrine hydrochloride. Nonetheless, numerous ads for Midol do create the impression

that Midol does not contain aspirin. This impression is created by ads which state that Midol and its ingredients are special and out-of-the-ordinary. For example, CX 302 states:

> Midol starts to work fast with an exclusive formula that helps stop periodic pain . . . and its medically approved ingredients gives effective relief from headache and low backache. All in all, Midol's unique formula gets you through those days in comfort.

The impression created by this ad is that Midol, and everything about it, is special and different. Its formula is described as "unique" and "exclusive." In the midst of language that creates an aura of uniqueness about the product, the ad states that Midol has a "medically-approved ingredient" to relieve pain. Consumers could reasonably infer that the "medically-approved ingredient," a part of the unique formula, is also unique. As respondent concedes, however, the "medically-approved" pain reliever is aspirin (Hartman, Tr. 9166), an ingredient," which is anything but unique or special (*see American Home Products*, 98 F.T.C. at 362), an ingredient which is familiar to most consumers. It would have been a simple matter for respondent to clarify its ads so that consumers would realize that it is the anti-spasmodic ingredient which is unique to Midol.

In another ad Midol is contrasted with "ordinary pain relievers." The ad (CX 296B) states, "An exclusive formula with medication ordinary pain relievers don't give you, Midol relieves the pain of backache, headache and other discomforts mature women can get." Although respondent contends that no other product has exactly the same formula as Midol and that ordinary pain relievers do not contain cinnamedrine hydrochloride, the ad has blurred the distinction between ingredients that relieve pain and those that perform another function. The impression created thereby is that the pain relieving medication

in Midol is not contained in ordinary pain relievers. Aspirin is a common (*i.e.*, ordinary) pain reliever. Therefore, CX 296B creates the false impression that Midol does not contain aspirin.[51]

The ads cited above could reasonably mislead consumers into believing that Midol does not contain aspirin. A misleading claim or omission will violate the FTC Act only if the omitted information (in this case, that Midol contains aspirin) would be a material factor in a consumer's purchasing decision. *F.T.C.* v. *Colgate-Palmolive Co.*, 380 U.S. at 392. Section 15 of the FTC Act provides that an omission of fact may be material "in the light of representations made or suggested . . . or . . . with respect to consequences which may result from the use" of the product. The failure to disclose the presence of aspirin is material in light of "representations made or suggested" in respondent's ads which create the impression that the pain reliever in Midol is unique. Is this false impression which would lead a consumer to look no further for a non-aspirin-based analgesic. It is this same false representation of uniqueness which would discourage a consumer from looking for a less expensive analgesic.

Expert testimony in this case explains one reason why consumers look for non-aspirin-based pain relievers. Aspirin may cause numerous side effects. According to Dr. Grossman, an expert in gastroenterology, aspirin may cause dyspepsia and gastrointestinal bleeding, and it may exacerbate or even cause ulcers. (Tr. 7471, 7479, 7720, 7722) According to Dr. Stevenson, an expert in asthma and immunology, aspirin, even in minute doses, can cause asthmatics to suffer attacks which may be severe or even life-threatening. (Tr. 1480, 1489) In addition, aspirin can

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[51] Similar ads are CX 297, 300. On the other hand, CX 305 indicates that it is the anti-spasmodic that is not contained in ordinary pain relievers and CX 306 makes it clear that it is the anti-spasmodic that is exclusive.

cause skin reactions such as hives or swelling. (Stevenson, Tr. 1511-12)

Respondent argues that the ALJ greatly inflated the number of consumers who would suffer adverse reactions from aspirin. (Sterling Reply Brief, pp. 48-50) However, as we found in *American Home Products*, 98 F.T.C. at 367, the number of consumers who suffer adverse reactions to aspirin is significant. Immunologists generally warn all asthmatics to avoid aspirin, regardless of whether they are known to be aspirin-sensitive (Farr, Tr. 2606) and respondent concedes that there are at least two to six million asthmatics in the United States (Sterling Reply Brief, p. 50). Thus, some consumers avoid aspirin for medical reasons. For them, Sterling's failure to disclose aspirin's presence is material in the context of ads which create the impression Midol is aspirin-free.

The nondisclosure of aspirin is also material for economic reasons. At the time Sterling disseminated the challenged Midol advertising, Midol was substantially more expensive than most other aspirin-based analgesics. In fact, the *wholesale* price of Midol was twice as expensive as the *retail* price of Bayer and more than four times as expensive as the average retail price for non-Bayer aspirin. (F. 6, 11) Since Midol ads create the false impression that its pain reliever is unique and, therefore, not available in other products, consumers are not as likely to consider less expensive aspirin-based analgesics available on the market as potential alternatives to Midol. Thus, failure to disclose aspirin's presence is material in the context of ads which imply that the analgesic in Midol is available in no other product.

We also find that consumers are not already aware of the ingredients in the analgesics which they use. This lack of knowledge is demonstrated by several studies in the record including an informal study conducted by Dr.

Moertel (Tr. 6355-60) and a 1970 Analgesic Segmentation Study (CX 394) performed at Sterling's request, which showed that 82% of those surveyed were unable to name any of the ingredients in the brand-name headache remedy they normally use. Sterling argues that the results of these studies do not prove that consumers are unaware of the contents of analgesics because the results are not projectible to the general population. (Sterling Reply Brief, p. 49) While it is true that these survey results may not be statistically projectible, they at least suggest that consumers are unaware of the ingredients in analgesics. (Pernica, Tr. 1998) In light of the fact that respondent has offered no contrary evidence, we are unwilling to conclude that consumers generally know which analgesics contain aspirin.

We stress that we find a violation of the FTC Act only in those instances in which Sterling affirmatively represented (either expressly or by implication) in its advertising that Midol did not contain aspirin. As we indicated in *Bristol-Myers*, slip op. at 54 [102 F.T.C. at 361], we do not find that the mere failure to disclose the presence of aspirin in advertising for aspirin-based analgesics is misleading. And, indeed, there are numerous ads in the record which do not misrepresent Midol's (or Cope's, or Vanquish's) aspirin content. These ads are silent on the subject. After viewing ads such as these, consumers would not necessarily know (based upon the ads) whether the advertised product contained aspirin. If consumers viewing these ads were concerned about aspirin content, they would have to look elsewhere for the information, but at least they would not be discouraged from doing so. On the other hand, in the context of the affirmative claims made in the Midol ads, the failure to disclose the presence of aspirin

is a material omission of fact which renders the advertisement false.[52]

V. Cope's Unique Formula

Paragraph 22 of the complaint charges that respondent falsely represented that Cope's formula is unique. The ALJ found that this representation had been made, and we agree. For example, CX 274 states:

> Cope looks different, is different. Besides a powerful pain reliever, Cope gives you a gentle relaxer. The others don't. . . . A unique formula for really effective relief of nervous tension headache. And you get it only in Cope.

CX 275 also represents that the Cope formula is "unique." These ads were shown to the public from December 1969 through March 1970. (CX 633)

The Cope ads mentioned above state that the Cope formula is unique because only Cope contains both "a powerful pain reliever" and also "a gentle relaxer." The clear message is that no other analgesic contains both types of ingredients. The ingredients in Cope are aspirin, caffeine, methapyrilene fumarate, and two antacids. Thus, the "powerful pain reliever" is aspirin and the "gentle relaxer" is metapyrilene fumarate, an antihistamine which, as explained above (*supra* p. 44) produces drowsiness. At the same time as Sterling was advertising Cope, Bristol-

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[52] Paragraph 26 of the complaint also alleges that Sterling represented that the stimulant in Midol is not caffeine. However, the record does not contain any evidence indicating that knowledge of the presence of caffeine in an OTC analgesic is material to consumers, the ALJ made no findings on that issue, and complaint counsel have not appealed that point. Therefore, we dismiss that portion of paragraph 26 that relates to caffeine.

Myers was promoting Excedrin P.M., an OTC analgesic which contained, among other things, both aspirin and methapyrilene fumarate. (CX 357B; *see also Bristol-Myers*, slip op. at 50. [102 F.T.C. at 358]) Thus, Excedrin P.M. also contained the "powerful pain reliever" and the "gentle relaxer." Furthermore, the evidence shows that at the time Sterling was advertising that only Cope contained a "powerful pain reliever" and "a gentle relaxer," it was aware that Bristol-Myers was marketing Excedrin P.M. (CX 678 Admission 1069) and it was aware that Excedrin P.M. contained aspirin and methapyrilene fumarate. (CX 357) Therefore, advertisements that portrayed Cope as unique were false and misleading. As explained in Part IV above, such false representations of uniqueness are material because they discourage consumers from shopping for potentially less expensive alternatives.

VI. Inconsistent Claims

Paragraph 17 of the complaint charges that respondent made several mutually inconsistent claims for its products. Specifically, it charges that respondent claimed in its ads that: (1) Bayer is as effective for the relief of headache pain as any other OTC analgesic, and Vanquish is a more effective reliever of headache pain than aspirin; (2) Bayer will cause stomach upset no more frequently than any other OTC analgesic, and Vanquish will cause less stomach upset than unbuffered aspirin; and (3) Bayer is as effective a reliever of nervous tension headache as any OTC analgesic, and Cope is more effective for the relief of nervous tension headache than any other OTC analgesic. Paragraph 29 charges that the making of inconsistent contemporaneous claims is unfair or deceptive. The ALJ disagreed and dismissed paragraph 17 and that portion of paragraph 29 that relates to inconsistent claims. From this determination, complaint counsel have appealed.

Complaint counsel's argument is based upon the Commission's decision in *Pfizer*. They argue that in order to substantiate advertising claims *Pfizer* requires an advertiser to possess a reasonable basis consisting of evidence that "would satisfy a reasonable and prudent businessman, acting in good faith, that such representation is true." 81 F.T.C. at 64, quoted at C.A.B. p. 64. This standard, complaint counsel contend, precludes the making of inconsistent claims because, having made a claim for one product, no advertiser could reasonably make an inconsistent claim for a competing product which it also sold to the public. Reasonableness, complaint counsel argue, cannot be judged solely in terms of the quantity of evidence supporting a given claim. (C.A.B. p. 65) Such conduct would be both unfair, because it places on the consumer the burden of taking the gamble as to which claim is correct, and deceptive, because the making of a claim implies the existence of a reasonable basis.

Finally, complaint counsel argue that on numerous occasions in the past the Commission has determined that the making of mutually inconsistent claims constituted a violation of the F.T.C. Act. To support this, they cite cases such as *Rudolph R. Siebert,* 49 F.T.C. 1418 (1953); *Montgomery Ward & Co., Inc.,* 70 F.T.C. 52 (1966), *aff'd,* 379 F.2d 666 (7th Cir. 1967); and *Sears, Roebuck and Co.,* 95 F.T.C. 406 (1980), *aff'd,* 676 F.2d 3985 (9th Cir. 1982).

After carefully considering complaint counsel's arguments, we conclude that it would be inappropriate for us to find that respondent violated the F.T.C. Act merely because it made inconsistent advertising claims. We believe the inconsistent claims theory would be a new theory of advertising substantiation which would shortcut and be contrary to principles of law set forth in *Pfizer* and its progeny. Thus, for the reasons set forth below, we agree with the ALJ that paragraph 17 and that portion of para-

graph 29 of the complaint that relate to inconsistent claims should be dismissed.

Complaint counsel argue that *Pfizer* requires not only an adequate quantity of support to substantiate claims but also support of a type that would satisfy a reasonable businessman that the claim is true. Inconsistent claims, complaint counsel contend, could never be reasonably substantiated because a reasonable businessman would never believe that two inconsistent claims were both true. The reasonable businessman standard quoted by complaint counsel actually comes from *H.W. Kirchner*, 63 F.T.C. 1282, 1294, and was restated by the Commission in *Pfizer*, 81 F.T.C. at 64. After quoting the substantiation standard from *Kirchner*, the opinion in Pfizer makes it clear that the *Pfizer* "test evaluates both the reasonableness of an advertiser's actions and the adequacy of the evidence upon which such actions were based." 81 F.T.C. at 64. Thus, the reasonable basis standard in *Pfizer* subsumes the *Kirchner* standard. Each individual advertising claim alleged in paragraph 17 could have been evaluated under the *Pfizer* standard. The performance of this analysis would have determined whether Sterling's reliance on the substantiation it possessed was reasonable. However, the reasonable basis analysis does not determine whether a claim is true. *See Pfizer*, 81 F.T.C. at 67 n. 22. Therefore, it is at least theoretically possible that two inconsistent claims could both be substantiated with a reasonable basis. In effect, the approach recommended by complaint counsel would bypass the *Pfizer* analysis in favor of a rule finding liability based solely upon the wording of advertising, regardless of the substantiation possessed by the advertiser.

The inconsistent claim theory would also produce an anomalous result described in respondent's answering brief. (R.An.B. p. 54) If an advertiser made inconsistent claims regarding products A and B, the advertiser would have automatically violated the F.T.C. Act. If, however,

one advertiser made the claim regarding product A and a competing advertiser made the inconsistent claim regarding product B, the claims would be judged under a reasonable basis standard and it is possible that neither advertiser would be found to have violated the law. By applying the reasonable basis standard to all claims, regardless of the advertiser, the above result can be avoided.

Finally, we find that the previous Commission cases cited by complaint counsel do not actually apply the inconsistent claim theory proposed by complaint counsel. A good example is the *Sears* case. In that case, Sears advertised that no pre-soaking was necessary prior to washing dishes in the Lady Kenmore dishwasher. The owner's manual, however, said just the opposite. The Commission held that Sears lacked a reasonable basis for its claim and entered an order which, among other things, prohibited Sears from making any claims in its advertising that were contradicted in an owner's manual given to a consumer after purchase. Complaint counsel contend that this is an example of the inconsistent claim theory. However, the Commission (and the ALJ) in *Sears* carefully examined the substantiation possessed by Sears and determined that it did not have a reasonable basis for its claim. 95 F.T.C. at 426-469, 514. The fact that the owner's manual contained inconsistent statements was merely a factor considered in determining whether the advertising was adequately substantiated. The analysis performed in *Sears* was not the abbreviated inconsistent claim analysis proposed by complaint counsel.

Thus, we find that the inconsistent claim theory is not appropriate for analyzing advertising substantiation. The advertising claims set forth in paragraph 17 of the complaint could have been each individually challenged for lacking a reasonable basis under *Pfizer*. Since this was not done, we agree with the ALJ that complaint paragraph 17

and that portion of paragraph 29 relating to inconsistent claims should be dismissed.[53]

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[53] Sterling has also raised objections to several of the ALJ's evidentiary rulings. First, it objects because the ALJ refused to admit into evidence approximately 160 scientific articles. (R.A.B. pp. 71-74) We find that this decision was an appropriate exercise of the ALJ's duty to manage a complex lawsuit. Although 160 articles were excluded, approximately 60 were accepted and the ALJ gave respondent the opportunity to select which articles would be admitted. (Tr. 11937-38, 18055) Furthermore, the ALJ permitted respondent's experts to quote from any of the articles and to read any passage into the record. (Tr. 11938)

Sterling also appealed the ALJ's exclusion of six unpublished scientific studies from the record. (R.A.B. 74-77) Two of the studies, RX 195 and 207, involve nonclinical tests submitted by Sterling to show it possessed a reasonable basis for superiority claims regarding Bayer. However, as we explained above (*supra* p. 38), because these claims were embellished with representations of establishment, only well-controlled clinical tests can constitute a reasonable basis for Bayer's superiority. Respondent was not harmed by the ALJ's rejection of RX 415 because that exhibit was submitted to support the claims of Bayer's superior quality and we held that complaint counsel failed to meet their burden of proof on that issue. RX 197 was rejected as being duplicative of other evidence on the record. The ALJ did, nonetheless, permit testimony regarding the study (*e.g.* Fields, Tr. 16758-61). There is no evidence that respondent was prejudiced by this evidentiary decision. RX 190 was rejected by the ALJ because it was unpublished, the author was reporting on a study by someone else, and Sterling called no foundation witness. Without a proper showing of reliability, rejection of RX 190 was proper. *Bristol-Myers*, 85 F.T.C. 688, 743-744 (1975). Finally, respondent was not prejudiced by the rejection of RX 422. The record shows that RX 422 was not complete (Tr. 17921-27) and, although given the opportunity to have the study's author testify (Tr. 15082), respondent chose not to call him. Nonetheless, the ALJ did admit an abstract of the complete study. (Tr. 17926-27) Thus, there was no error in the rejection of RX 422.

VII. Liability of Lois Holland Callaway

The complaint in this case charges the advertising agency, Lois Holland Callaway, Inc., with responsibility for certain advertising claims regarding Vanquish. We dismiss each of these charges since we have ruled that the ads in question were not deceptive.

Specifically, paragraph 8 charges the agency with falsely representing it has been established that Vanquish is more effective than aspirin and less likely to cause stomach upset than unbuffered analgesics. However, as we indicated above, (*supra* pp. 16-19) the challenged advertising contains no establishment representations regarding Vanquish. In paragraph 12, Lois Holland Callaway is charged with representing that Vanquish is a more effective pain reliever and less likely to cause stomach upset, without disclosing that a substantial question existed among experts as to the validity of these claims. For reasons explained above (*supra* p. 37), we dismissed all claims based on the substantial question theory. In paragraph 23, Lois Holland Callaway is charged with failing to disclose in advertising the presence of aspirin and caffeine in Vanquish. As we explained above (*supra* p. 45), this would constitute a violation of the FTC Act only if the advertising also represented or implied that Vanquish did not contain aspirin. We found that Vanquish advertising created no such implication. We therefore have dismissed all unfair or deceptive advertising claims with which Lois Holland Callaway has been charged.

VIII. Relief

The order we enter today proscribes the violations of the FTC Act committed by respondent. It also prohibits related violations in order to assure respondent's future compliance. *F.T.C.* v. *Ruberoid Co.*, 343 U.S. 470, 473 (1952); *American Home Products*, 98 F.T.C. at 398.

However, there are differences between our order and the one entered by the ALJ. First, we dismissed those allegations of the complaint based upon the substantial question theory of advertising substantiation. The ALJ's order would have required respondent either to substantiate all comparative efficacy claims with well-controlled clinical tests, or to disclose in ads making those claims that the claims had not been proven. Our order imposes the clinical testing requirement only on those ads which claim that an analgesic's superiority has been established.

Second, the ALJ's order required that respondent possess a reasonable basis for any claim it makes regarding any nonprescription drug. We decline to enter so broad an order provision. However, since we have found instances in which respondent lacked an appropriate level of substantiation for both comparative and noncomparative therapeutic performance claims, our order requires Sterling to possess a reasonable basis for any therapeutic performance claim it makes regarding an OTC internal analgesic.

The ALJ also entered an order provision imposing specific substantiation requirements for all claims regarding pharmaceutical quality. (I.D. pp. 353-354) As we discussed above, we found that complaint counsel failed to meet its burden of showing that respondent lacked adequate substantiation for its claims regarding Bayer's overall pharmaceutical quality. Accordingly, we have limited this order provision to claims regarding specific product attributes. These were the only claims related to pharmaceutical quality which complaint counsel showed respondent failed to substantiate. Additionally, our order narrows the scope of the aspirin disclosure required by the ALJ, limiting the disclosure of aspirin's presence to those ads for analgesics which contrast the advertised product with aspirin. Finally, we have limited the product coverage of some of

the order provisions. Each of these modifications is discussed below.

A. Establishment Claims.

Paragraph I of the order sets forth the level of support which Sterling must possess before it can advertise that the superior effectiveness of any nonprescription internal analgesic product has been established. These types of claims must be supported by two well-controlled clinical studies meeting the criteria set forth in subparagraphs A-C of paragraph I. Testimony in this case shows that experts require studies to meet these criteria in order to establish an analgesic's superior efficacy. (*Supra* pp. 21-32) Indeed, we imposed the same testing requirement in *American Home Products* and *Bristol-Myers* based upon the expert testimony elicited in those cases. However, as in *Bristol-Myers,* slip op. at 67 [102 F.T.C. at 372], we have included paragraph I D in order to avoid penalizing Sterling for purely technical instances of noncompliance with the detailed provisions of paragraph I, if Sterling can show that the scientific community would not regard the violation as affecting the adequacy of support for the claims.

The ALJ's order applied the clinical testing requirement to establishment claims made by Sterling regarding any nonprescription internal analgesic product and we agree with this product coverage. Complaint counsel have argued that the clinical testing requirement should apply to establishment claims regarding all OTC drugs. (C.A.B. pp. 27-35) However, we rejected similar arguments in both *Bristol-Myers* and *American Home Products.* As we held in *American Home Products,* 98 F.T.C. at 402-403, it is possible that claims of superiority for other drug products may be established by other than two well-controlled clinical tests. Indeed, there is testimony in this case that nonclinical tests can establish the efficacy of antacids. (Sco-

ville, Tr. 14476-81) Thus, it would not be appropriate for us to apply paragraph I of the order to all OTC drugs and we, therefore, limit its applicability to OTC internal analgesics.

On the other hand, we do not believe that application of this part of the order should be limited to the specific brands involved in this case, *i.e.*, merely to Bayer and Cope. In determining the breadth of an order provision, we must consider the extent of violations the transferability of the violations to other contexts, and any past history of violations. *See Sears, Roebuck and Co.* v. *F.T.C.*, 676 F.2d 385, 391-396 (9th Cir. 1982).

Respondent's violative ads were widely disseminated over several years. For example, the advertisements representing that Bayer's therapeutic superiority had been established were disseminated more than 2,600 times over a 29-month period. Also, respondent Sterling does have a previous history of dealings with the F.T.C.[54] Finally,

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[54] In 1950, the Commission entered a litigated order against Sterling based in part upon false advertising representations made regarding Bayer Aspirin. *Sterling Drug, Inc.*, 47 F.T.C. 203 (1950). In that case the Commission entered an all products order against Sterling. 47 F.T.C. at 214. On four occasions subsequent to that litigation, Sterling had consented to the entry of cease and desist orders. 49 F.T.C. 1635 (1953) (efficacy claims regarding "Campho-Phenique"); 61 F.T.C. 1008 (1962) (false representations regarding the safety of "Isuprel," a drug for oral inhalation); 73 F.T.C. 979 (1962) (false representations regarding the efficacy of a dietary supplement, "Super Ironized Yeast"); 84 F.T.C. 547 (1974) (false claims regarding medical benefits from using the spray disinfectant, "Lysol"). We do not take these consent orders as evidence of prior guilt. However, they are relevant for determining the appropriate scope of relief. Each of those consent orders applied not only to the product which had allegedly been falsely advertised, but also to other similar products. Thus, in no instance has an order entered against Sterling been limited

and most important, it is clear that respondent could easily change the names of some of its products or make inadequately substantiated claims of established superiority regarding other OTC internal analgesics. The evidence shows that respondent made inadequately substantiated establishment claims regarding both Bayer and Cope. Although we did not find a violation, the record also shows that respondent made claims of therapeutic superiority for Vanquish. Thus, our order requires all claims of established comparative efficacy made by Sterling regarding OTC internal analgesics to be substantiated by two well-controlled clinical tests.

In numerous previous cases the Commission has issued (and courts have upheld) cease and desist orders applying to all of a company's products based upon violations committed in the advertising of only one, or a few, products. *E.g., Litton Industries, Inc.*, 97 F.T.C. 1 (1981), *aff'd*, 676 F.2d 364 (9th Cir. 1982) (misrepresentations regarding microwave oven, order applied to any product used for personal or household purposes); *Sears, Roebuck and Co.*, 95 F.T.C. 406 (1980), *aff'd*, 676 F.2d 385 (9th Cir. 1982) (misrepresentations regarding dishwasher, order applied to 12 major home appliances); *Jay Norris Corp.*, 91 F.T.C. 751 (1978), *aff'd*, 598 F.2d 1244 (2d Cir. 1979), *cert. denied*, 444 U.S. 980 (1979) (misrepresentations regarding six products, order covered general mail order merchandise); *Porter & Dietsch, Inc.*, 90 F.T.C. 770 (1977), *aff'd*, 605 F.2d 294 (7th Cir. 1979), *cert. denied*, 445 U.S. 950 (1980) (one product was misrepresented, order covered any good, drug, cosmetic or device); and *I.T.T. Continental Baking Co.*, 83 F.T.C. 865 (1973), *modified on other grounds*, 523 F.2d 207 (2d Cir. 1976) (Wonder Bread was misrepresented, order applied to any food product). The coverage

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in its scope solely to the product which was the subject of the proceeding.

of this order provision is much more narrow, applying only to other OTC internal analgesics.[55]

Paragraph II of our order applies to establishment claims which respondent makes regarding Bayer's superior pharmaceutical quality. Complaint counsel argue that these claims must be substantiated with well-controlled clinical studies because all claims of superior pharmaceutical quality imply therapeutic superiority. (C.A.B. pp. 9-27). However, as we explained above, we do believe that consumers can understand pharmaceutical or manufacturing quality (if properly characterized) as a concept separate from therapeutic superiority. It is true that many of respondent's ads which claim that Bayer is pharmaceutically superior also impliedly represent that it is therapeutically superior. But there are other ads which make representations regarding Bayer's pharmaceutical quality only. As we discussed in the liability section, Sterling's ads claimed that its tests demonstrated both Bayer's overall pharmaceutical superiority to other aspirin as well as its superiority in terms of four specific attributes (purity, freshness, stability and speed of disintegration). Complaint counsel failed to meet its burden of showing that the tests Sterling performed do not establish Bayer's overall pharmaceutical superiority. They also failed to show what sort of evidence experts require to establish the pharmaceutical superiority of an analgesic. It is, therefore, inappropriate for us to enter any order provision detailing a specific level of substantiation which Sterling must possess when it represents that Bayer is pharmaceutically superior.

Nonetheless, even a facial examination of respondent's support for its claims shows that other brands of aspirin

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[55] According to material submitted by Sterling to the Physician's Desk Reference (36th ed. 1982), as of 1982 Sterling manufactured 5 OTC internal analgesics.

were at least as pure, as fresh, as stable and as quick to disintegrate as Bayer. Thus, Sterling does not possess support demonstrating or establishing Bayer's superiority with respect to those attributes. Paragraph Part II of our order accordingly requires that when respondent represents that it has been established that an OTC internal analgesic is fresher, purer, more stable, or quicker to disintegrate than others, it must possess support for that claim which would satisfy relevant experts that the product has the superiority attributed to it. However, at this time we reach no conclusion as to what type or what quantity of evidence is necessary to satisfy that burden.

B. Reasonable Basis Provision.

Paragraph III of our order requires Sterling to possess a reasonable basis for all therapeutic performance claims regarding OTC internal analgesics. As a practical matter, this paragraph applies primarily to those claims that are not presented (either expressly or implicitly) as claims whose truth has been scientifically established. For establishment claims, Sterling will be held to the more specific standards set forth in Paragraph I, so Paragraph III adds nothing to Sterling's obligations with respect to establishment claims. The purpose of Paragraph III is to hold Sterling to a more general reasonable basis standard for all other "non-establishment" claims.

A similar provision was entered in our order against Bristol-Myers (slip op. at pp. 70-73) [102 F.T.C. at 374-377], and our reasons for entering one here is very similar. While we are unwilling to go as far as the ALJ's order, which would have imposed a reasonable basis requirement for all claims for all nonprescription drugs, we believe that a requirement limited to therapeutic performance claims for OTC analgesics is reasonably related to the violations found. Most of the claims in the case were establishment claims and we found that Sterling did

not possess adequate substantiation for any of those claims. Our concern is that this violation, the making of inadequately substantiated claims, can easily be transferred to other sorts of claims, including non-establishment claims.

Moreover, in this case the record shows that respondent has already made a number of non-establishment claims without possessing the evidence required to satisfy the reasonable basis standard. We found ten such violations in its tension relief advertisements for Cope, and another 16 violations in similar advertisements for Midol (*supra* at p. 39). As we noted in *Bristol-Myers,* such a record (combined with the other factors dismissed in the previous section, such as the history of prior violations) might well justify an order extending to all claims or to all nonprescription products. Instead, we are limiting this provision to therapeutic performance claims for OTC analgesics—*i.e.,* to the exact product category and claims involved in this case. Paragraph II, thus, has a much closer relation to the violations involved here than did the broader reasonable basis provision that was struck down on appeal in *American Home Products* v. *FTC,* 695 F.2d at 710-711.

Finally, we note that paragraph III specifies that two well-controlled clinical tests will always be sufficient to constitute a reasonable basis, but it also permits Sterling to satisfy this requirement with any other "competent and reliable evidence" sufficient to provide a reasonable basis for the challenged claim. While this more general standard does leave some ambiguity regarding the absolute minimum level of evidence required to satisfy paragraph III, some flexibility is inherent in any reasonable basis order. For the reasons already discussed at length in our *Bristol-Myers* opinion (slip op. pp. 71-73) [102 F.T.C. at 375-377], we believe that the flexibility provided by paragraph III represents an appropriate balance between the need for clear standards and the need to prevent repeated violations. Should Sterling ever be in doubt about the level of evi-

dence required for any further claim, it can always: (a) take advantage of paragraph III's "safe harbor" by conducting two well-controlled clinical tests; (b) request an advisory opinion from the commission pursuant to Rule 2.41; or (c) qualify its advertising claim to make consumers aware of the lower level of substantiation.

C. Ingredient Claims and Omissions.

Sterling's advertisements falsely represented that the pain reliever in Midol was special or unique and that Cope was the only OTC analgesic containing both a pain reliever and a sedative. (*supra* pp. 45-49) Under Paragraph IV of the order, Sterling may not represent that a product contains any special, unusual or unique ingredient or ingredients when the same ingredients are used in other nonprescription drug products intended for the same purpose. This is the only provision of our order which we believe should apply not only to claims regarding analgesics but to advertising claims made by respondent regarding any nonprescription drug. In determining the scope of this provision, we have considered the same factors discussed in connection with paragraphs I and II of the order. First and foremost, as we discussed in *Bristol-Myers*, a false claim regarding ingredients could be made for any drug product. Second, documents from Sterling's files show it was fully aware that Cope's ingredients were not unique and that another analgesic on the market, Excedrin P.M., contained both a pain reliever and a sedative. Third, as we discussed above, this is the second time a cease and desist order has been entered against Sterling regarding the advertising of its OTC analgesics. These reasons justify entry of a broad order provision applying to all nonprescription drugs advertised by Sterling.[56]

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[56] According to material submitted by Sterling to the *Physician's Desk Reference for Nonprescription Drugs* (1st ed. 1980) as of 1980, Sterling manufactured 36 nonprescription drug products.

In its appeal brief, respondent argues that entry of any order provision applying to all drugs is unjustified because there is no showing that Sterling has a history of past violations. In addition, Sterling assures us that its advertising claims were all made in good faith. (R.A.B. pp. 77-80) However, in determining the appropriate scope of order provisions, we consider all the factors discussed in *Sears*. Taken in conjunction, the ease with which the violation could be transferred to other drugs, Sterling's past history of violative advertising, and the fact that it appears Sterling knew its Cope ads were false all justify entry of an order applying to all drugs.

The purpose of paragraph V is to prevent respondent from passing off its aspirin-based analgesic products as being different from aspirin or from otherwise misrepresenting the identity of any analgesic ingredient. The principal means by which this deception has been accomplished in the past, has been to create the impression that some analgesic ingredient in respondent's product is different from the ingredient in any competing analgesic. To prevent this practice, paragraph V prohibits any misrepresentation that the analgesic ingredient in an aspirin-containing product is different from aspirin. To prevent closely related violations, the order prohibits misrepresentations regarding the identity of any analgesic ingredient in respondent's products. The order also makes clear that any attempt to contrast with aspirin the ingredient in an aspirin-based analgesic without disclosing that the ingredient in respondent's product is also aspirin, will violate the order.

The ALJ's order would have required the disclosure of aspirin's presence in any ad for an aspirin-based analgesic. However, nondisclosure of aspirin constitutes a violation only in those instances in which respondent falsely represents that the advertised product does not contain

aspirin. Thus, paragraph V is specifically tailored to prevent the sort of violation committed by respondent.

D. Labeling.

The order entered by the ALJ in this case applied not only to respondent's advertising, but also to the labeling of its products. As we stated in both *American Home Products,* 98 F.T.C. at 411, and *Bristol-Myers,* slip op. at p. 76 [102 F.T.C. at 380], our liaison agreement with the FDA recognizes that primary responsibility for labeling of nonprescription drug rests with that agency. For the reasons we set forth in *American Home Products,* the order which we enter does not apply to labeling.

E. Corrective Advertising.

In their appeal brief, complaint counsel request that we impose a corrective advertising requirement on Sterling and require it to include a notice in its advertising disclosing that Bayer has not been proven therapeutically superior to other aspirin. (C.A.B. pp. 37-60) The ALJ declined to require corrective advertising and we agree that it would not be appropriate in this case.

Corrective advertising is a remedy available to the Commission. *Warner-Lambert Co.* v. *F.T.C.,* 562 F.2d 749, 756-759 (D.C. Cir. 1977), *cert. denied,* 435 U.S. 950 (1978). Two inquiries must be made in order to determine if it is appropriate: (1) Did the advertisements in question play a substantial role in creating or reinforcing a false belief in the public's mind regarding the product; and (2) Will the belief remain after the advertising ceases? *Warner-Lambert Co.* v. *F.T.C., Id.* at 762. Based upon our analysis of the evidence in this case, we agree with the ALJ that it is not clear that respondent's advertising played a substantial role in creating or reinforcing a false belief regarding Bayer in the public's mind.

The record contains the results of several surveys which attempted to assess the public's image of Bayer. (F. 1240-1310). Two of these surveys are particularly significant. The first is the Assets and Liabilities Study, CX 395, which measured consumer attitudes regarding Bayer in 1967, prior to the dissemination of any of the ads which are the subject of this case. The other is the Zeisel Image Study, CX 521 which was conducted in 1975, after the dissemination of challenged ads. Although a comparison of the results of these two studies is apparently somewhat difficult to perform, complaint counsel concede that the results show that Bayer's image remained relatively stable throughout the eight-year period between the two studies. (C.A.B. p. 51) Based upon this, it is difficult to conclude that Sterling's advertising created or reinforced the public's belief regarding Bayer's superiority. Complaint counsel argue that even though the public's image of Bayer may have remained stable during the period, it nonetheless became "sharper," that is, more of those surveyed in 1975 had opinions than in 1967. To support this they cite the testimony of Dr. Brock, an expert, in the analysis of image studies. (Tr. 5155-59) Respondent countered Dr. Brock's testimony with the testimony of its own expert, Dr. Amstutz (Tr. 10164-90). We find this evidence regarding "sharpness" inconclusive and do not believe that it supports imposition of corrective advertising.

Complaint counsel also argue that the need for corrective advertising may be inferred directly from the advertising. We decline to draw such an inference in this case. Although the ads representing Bayer's comparative superiority were disseminated on several thousand occasions, we do not think that in this case that is adequate to justify corrective advertising. Indeed, the violative ads represent only a portion of the Bayer ads which appeared during the early 1970's. (The record contains nearly twice as many Bayer ads which did not represent its therapeutic

superiority.) In light of survey evidence which appears to indicate no need for corrective advertising, we find such a need may not be inferred directly from the ads.

Numerous factors contribute to a product's image. Included among these are consumers' experience with the product, publicity regarding the product, longevity and visibility in the market, amount of advertising (regardless of content), advertising content and other sources. (Miles, Tr. 9355-59) The longer a brand has been in existence, the less its image stems from one particular advertising campaign. (Miles, Tr. 9366) For a brand such as Bayer, which has been on the market for many years, familiarity is the primary influence on brand image. (Haley, Tr. 10569) Complaint counsel contend that this case is similar to *Warner-Lambert* in which the Commission ordered corrective advertising regarding Listerine, a well-established brand. (C.A.B. p. 42) However, in *Warner-Lambert,* the record showed that the respondent had been making false claims regarding Listerine in its advertising for more than 50 years and that throughout that period the false claim had been a major theme of the advertising, 86 F.T.C. 1398, 1501. The corrective advertising was designed to correct that false advertising. In this case, there has been no showing that the false advertising was so extensive. Sterling's false advertising was disseminated during only a 29-month period, and the public's image of Bayer remained stable during that period. Thus, since it has not been shown that Sterling's advertising created or reinforced the public's image of Bayer, corrective advertising is an inappropriate remedy.

X. Conclusion

For the reasons set forth above, the initial decision of the administrative law judge is modified as described. An appropriate order is appended.

Separate Statement of Commissioner Pertschuk Concurring in Part and Dissenting in Part *

For the reasons stated in my separate opinion in *Bristol-Myers* (D. 8917) [102 F.T.C. at 382], announced today, I dissent from that portion of the Commission's opinion which reverses the "substantial question" doctrine developed in *American Home Products,* 98 F.T.C. 136 (1981), *aff'd,* 695 F.2d 681 (3d Cir. 1982). Therefore, I dissent from the Commission's decision to dismiss paragraphs 12 through 14 of the complaint.

I also dissent from the portion of the Commission's opinion which dismisses complaint paragraphs 17 and 29, which allege that Sterling violated Section 5 by making contemporaneous inconsistent claims for its OTC internal analgesic drug products. The Commission dismisses these charges, not because Sterling did not make such claims, but because it sees the basis of the charge as a "new theory of advertising substantiation which would shortcut and be contrary to principles of law set forth in *Pfizer* and its progeny." Slip op. at 50. [102 F.T.C. at 358]

I disagree. The inconsistent contemporaneous claims allegation stems directly from the reasonable basis doctrine set out in *Pfizer.* In my view, application of the reasonable basis doctrine to an examination of the claims made by Sterling in this case leads inexorably to the conclusion that Sterling has made unsubstantiated claims in violation of Section 5.

The Commission agrees that Sterling represented that Vanquish was better than aspirin in relieving pain and in avoiding stomach upset (slip op. at 16, 18) [102 F.T.C. at 329, 331], and that Cope was superior to any OTC analgesic for the relief of nervous tension headache (slip

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* Statements by Chairman Miller and Commissioners Bailey and Douglas concerning this order were issued with the Final Order in *Bristol Meyers Co., et al.* See 102 F.T.C. 381, 386, 389.

op. at 20) [102 F.T.C. at 332]. At the same time it was making those claims, however, Sterling was *also* claiming that Bayer aspirin was just as good as *any* internal analgesic in relieving pain and nervous tension headaches, and avoiding stomach upset. (F. 398-402)

There is simply no way those statements can be reconciled. Sterling's claims that Vanquish and Cope were more effective than aspirin plainly conflict with Sterling's contemporaneous claim that Bayer aspirin was just as effective as any OTC internal analgesic—presumably, including Vanquish and Cope. Both statements can not be true at the same time.

Nevertheless, the Commission declines to find a violation on the ground that a reasonable basis analysis does not determine whether a claim is true, and that therefore it is "theoretically possible that two inconsistent claims can both be substantiated with a reasonable basis." Slip op. at 51. [102 F.T.C. at 358]

While it might be theoretically possible for two inconsistent claims to be adequately substantiated, the problem with the Commission's rationale is that it fails to consider whether it is even theoretically possible for each claim made by Sterling in *this case* to be adequately substantiated. It appears obvious to me that they cannot. If Sterling has a reasonable basis for a claim that Vanquish provides superior pain relief to aspirin, it cannot have a reasonable basis for a claim that Bayer aspirin relieves pain just as well as all OTC internal analgesics. Conversely, if Sterling has a reasonable basis for a claim that aspirin relieves pain just as effectively as all OTC internal analgesics, it cannot have a reasonable basis for a claim that Vanquish relieves pain better than aspirin. Where an advertiser makes an objective and verifiable claim that its product performs better than *any* other product, adequate substantiation for that claim necessarily precludes the advertiser from having a reasonable basis for a claim that

another product works better than, or as well as, the one advertised.

The Commission seems troubled, however, by the application of an "inconsistent contemporaneous claims" theory. It notes the apparent discrepancy between the case where a single advertiser is held liable for making inconsistent claims, and the case where the same claims are made separately by two different advertisers and the Commission finds each adequately substantiated. In fact, such a result would not be anomalous. Indeed, it would be perfectly consistent with the reasonable basis doctrine, which takes into account not only the sufficiency of the evidence on which an advertiser relies but also "the reasonableness of the advertiser's action and his good faith." *National Dynamics Corp.*, 82 F.T.C. 488, 553 (1973). In considering an advertiser's reasonableness, the Commission routinely considers information in the advertiser's possession which might give the advertiser reason to question the evidence relied upon to substantiate a claim. Clearly, an advertiser possessing data which directly contradicts a claim cannot have a reasonable belief in the truth of that claim. On the other hand, if the contradictory evidence exists but the advertiser is unaware of it and would have no reason to know about it, the advertiser would not be precluded from making the claim. In other words, whether or not there is liability depends, at least in part, on the advertiser's knowledge. The application of the inconsistent contemporaneous claims theory simply is one example of the effect of this standard, and accordingly reflects no deviation from the established reasonable basis doctrine.

It is true, as the majority notes, that we could have proceeded to determine *which* of Sterling's claims was the one that lacked a reasonable basis. But where the conclusion is inescapable, as it is here, that one claim or the other lacked a reasonable basis, it seems like a waste of resources to require both sides to go through the full

panoply of evidentiary exchanges just to find out which claim was the one to violate Section 5. Accordingly, I would have sustained the allegations of the complaint with respect to the making of contemporaneous inconsistent claims.

Final Order

The matter has been heard by the Commission upon the appeal of counsel for respondent Sterling Drug, Inc., and complaint counsel and upon briefs and oral argument in support of and in opposition to the appeals. The Commission, for reasons stated in the accompanying Opinion, has granted a portion of respondent's appeal and denied that of complaint counsel. Therefore

It is ordered, That the initial decision of the administrative law judge be adopted as the Findings of Fact and Conclusions of Law of the Commission except as is otherwise inconsistent with the attached opinion.

Other Findings of Fact and Conclusions of Law of the Commission are contained in the accompanying Opinion.

It is further ordered, That the following Order to Cease and Desist be entered.

Order

I

It is ordered, That Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or other nonprescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from:

Making any representation, directly or by implication, that a claim concerning the superior effectiveness of such product has been established or proven unless such representation has been established by two or more adequate and well-controlled clinical investigations, conducted by independent experts qualified by training and experience to evaluate the comparative effectiveness of the drugs involved, on the basis of which it could fairly and responsibly be concluded by such experts (1) that the drug will have the comparative effectiveness that it is represented to have, and (2) that such comparative effectiveness is demonstrated by methods of statistical analysis, and with levels of confidence, that are generally recognized by such experts. The investigations shall be conducted in accordance with the procedures set forth below.

At least one of the adequate and well-controlled clinical investigations to evaluate the comparative effectiveness of the drug shall be conducted on any disease or condition referred to, directly or by implication, or, if no specific disease or condition is referred to, then the adequate and well-controlled clinical investigations shall be conducted on at least two conditions or diseases for which the drug is effective. The clinical investigations shall be conducted as follows:

A. The subjects must be selected by a method that:

1. Provides adequate assurance that they are suitable for the purposes of the investigation, and the diagnostic criteria of the condition to be treated (if any);

2. Assigns the subjects to the test groups in such a way as to minimize bias; and

3. Assures comparability in test and control groups of pertinent variables, such as age, sex, severity or duration of disease or condition (if any), and use of drugs other than test drugs.

B. The investigations must be conducted double-blind, and methods of double-blinding must be documented. In addition, the investigations shall contain a placebo control to permit comparison of the results of use of the test drugs with an inactive preparation designed to resemble the test drugs as far as possible.

C. The plan or protocol for the investigations and the report of the results shall include the following:

1. A clear statement of the objective of the investigation;

2. An explanation of the methods of observation and recording of results, including the variables measured, quantitation, assessment of any subject's response and steps taken to minimize bias on the part of the subject and observer;

3. A comparison of the results of treatments or diagnosis with a control of such a fashion as to permit quantitative evaluation. The precise nature of the control must be stated and an explanation given of the methods used to minimize bias on the part of the observers and the analysts of the data;

4. A summary of the methods of analysis and an evaluation of data derived from the study, including any appropriate statistical methods.

D. A test or investigation which is not conducted in accordance with these procedures may be used to establish a claim only if respondent can show that, notwithstanding the failure to satisfy these procedures, the test or investigation would still be generally accepted by the relevant scientific community as sufficient to establish the truth of the claim.

II

It is further ordered, That respondent Sterling Drug, Inc., a corporation, its successors and assigns, and its of-

ficers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription internal analgesic product, in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication, that the superior freshness, purity, stability, or speed of disintgration of such product has been established, demonstrated, or proven unless at the time such representation is made, respondent possesses and relies upon competent and reliable scientific evidence which would permit qualified experts to conclude that the product has the comparative pharmaceutical qualities it is represented to have.

III

It is further ordered, That respondent Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, directly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol" or any other nonprescription internal analgesic, in or effecting Commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from making any therapeutic performance claim for such product unless respondent possesses a reasonable basis for making that claim. A reasonable basis for such a claim shall consist of competent and reliable scientific evidence supporting that claim. Well-controlled clinical tests conducted in accordance with the criteria set forth in Order Paragraph I shall be deemed to constitute a reasonable basis for a claim.

IV

It is further ordered, That respondent Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, dirctly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription drug product in or affecting commerce, as "commerce" and "drug" are defined in the Federal Trade Commission Act, do forthwith cease and desist from making any representation, directly or by implication that such product contains any unusual, special or unique ingredient or ingredients when such ingredient or ingredients are commonly used in other nonprescription drug products intended for the same use or uses as the product advertised by respondent.

V

It is further ordered, That respondent Sterling Drug, Inc., its successors and assigns, and its officers, agents, representatives and employees, dirctly or through any corporation, subsidiary, division or other device, in connection with the advertising, offering for sale, sale or distribution of "Bayer Aspirin," "Bayer Children's Aspirin," "Vanquish," "Cope," "Midol," or any other nonprescription internal analgesic in or affecting commerce, as "commerce" is defined in the Federal Trade Commission Act, do forthwith cease and desist from falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin or otherwise misrepresenting the identity of any analgesic ingredient. It shall be a violation of this paragraph to contrast the analgesic ingredient of a product which contains aspirin with the analgesic ingredient of another product if that product also contains

aspirin, unless respondent discloses clearly and conspicuously that the analgesic ingredient in its product is aspirin.

VI

It is further ordered, That respondent Sterling Drug, Inc., shall notify the Commission at least thirty (30) days prior to any proposed change in the corporation such as a dissolution, assignment or sale resulting in the emergence of a successor corporation, the creation or dissolution of subsidiaries or any other change in its corporation which may affect compliance obligations under this Order.

VII

It is further ordered, That the respondent herein shall within sixty (60) days after service of this Order upon it and at such other times as the Commission may require, file with the Commission a written report setting forth in detail the manner and form in which it has complied or intends to comply with this Order.

Complaint paragraphs Eight A.2, Eight B, Eight C, Ten B, Twelve, Thirteen, Fourteen, Fifteen A, Seventeen, Twenty-Three, Twenty-Four, and that portion of Twenty-Nine which refers to Seventeen are hereby dismissed.

FTC ORDER DENYING PETITION FOR RECONSIDERATION

Dated October 14, 1983

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: James C. Miller III, Chairman
David A. Clanton, Michael Pertschuk
Patricia P. Bailey, George W. Douglas

Docket No. 8919

In the Matter of

STERLING DRUG, INC., a corporation,
DANCER-FITZGERALD-SAMPLE, INC., a corporation, and
LO'S HOLLAND CALLAWAY, INC., a corporation.

Order Denying Respondent Sterling Drug's Petition for Reconsideration

An opinion and final order in this matter were issued on July 5, 1983. Respondent Sterling Drug was served with the opinion and order and petitioned for reconsideration thereof on August 8, 1983. The Commission, for the reasons stated in the accompanying opinion, has determined to deny Sterling Drug's Petition for Reconsideration. Therefore,

IT IS ORDERED, that Respondent Sterling Drug's Petition for Reconsideration be, and hereby is, dismissed.

By the Commission.

/s/ EMILY H. ROCK
Emily H. Rock
Secretary

SEAL

ISSUED: October 14, 1983

UNITED STATES OF AMERICA
BEFORE FEDERAL TRADE COMMISSION

COMMISSIONERS: James C. Miller III, Chairman
David A. Clanton, Michael Pertschuk
Patricia P. Bailey, George W. Douglas

Docket No. 8919

In the Matter of

STERLING DRUG, INC., a corporation,
DANCER-FITZGERALD-SAMPLE, INC., a corporation, and
LOIS HOLLAND CALLAWAY, INC., a corporation.

Opinion of the Commission

By Clanton, Commissioner:

Respondent Sterling Drug Inc. ("Sterling") has filed a Petition for Reconsideration seeking to delete Paragraphs II, III and V of the order that we entered against it on July 5, 1983. For the reasons stated below, the Petition is denied in its entirety.

Paragraph II of the order prohibits Sterling from representing that the superior freshness, purity, stability or speed of disintegration of a nonprescription analgesic has been established unless Sterling possesses a reasonable basis for such a claim. In petitioning for reconsideration, Sterling contends that its advertising did not make superior freshness, purity, stability or speed of disintegration claims; that we misinterpreted test results for two other aspirin brands, and improperly disregarded factors other than test results relating to physical integrity of the tablets; and that the record does not demonstrate a propensity to make future claims regarding specific pharmaceutical attributes.

We reject Sterling's assertion that its advertising made no superior freshness, purity, stability, or speed of disintegration claims. Sterling, having had adequate opportunity to argue the meaning of its advertisements in its appeal from the administrative law judge's initial decision, cannot challenge our interpretation of the advertisements in petitioning for reconsideration of our final order. See 16 C.F.R. § 3.55.

With respect to the substantiation for these claims, Sterling contends (1) that the Parke-Davis test results should be disregarded because they included an inadequate number of samples; (2) that the test results of the Safeway and Safeway S Brands should be grouped together and that when so combined, the results demonstrate Bayer's superiority; (3) that we considered an improper mix of test results in determining that Bayer was not fresher, purer, or more stable; and (4) that we should have considered factors other than the actual speed of disintegration in determining whether Bayer was quicker to disintegrate.

Each of these contentions is without merit. First, the test results may be inconclusive, because of the limited sample size, to demonstrate the Parke-Davis brand's superiority. Sterling has charged, however, with falsely representing that tests established Bayer's superiority over other tested brands. See Slip op. at 14. That representation was clearly false. Secondly, we decline Sterling's belated invitation to combine the test results. Sterling's own tests treat the Safeway and Safeway Super S brands separately. See Ex. 430. Thirdly, we see no reason to reverse the position that we took in our opinion concerning which tests were relevant to Sterling's claims that Bayer was fresher, purer, and more stable. In order to determine which mix was appropriate, we relied on the testimony of Dr. Rhodes, an expert in drug formulation and evaluation, and of Sterling's own chemist. See Slip op. 33-35. Sterling,

on the other hand, has not cited anything in the record to support its claim that the mix of test results was improper. Lastly, Sterling's contention that the Commission erred in failing to consider that disintegration time can easily be shortened by taking steps that will cause more breakage and deterioration fails to take into account the actual representations that were made.

The advertisements claimed simply that Bayer was quicker to disintegrate than other leading brands (Slip op. at 14). Sterling made no attempt to qualify those claims or to explain that this representation must be considered in light of other factors. Furthermore, in determining whether a particular aspirin brand disintegrates rapidly enough to be marketed, the United States Pharmacopoeia examines the actual speed of disintegration, not the other factors mentioned by Sterling.

Sterling next objects that Paragraph II is inappropriate because the Commission has no reason to anticipate that it will make future claims regarding specific pharmaceutical attributes. Abandonment of a practice does not, however, preclude entry of an order provision prohibiting the practice. Paragraph II is carefully tailored to prohibit precisely the types of violations that Sterling has committed.

Finally, none of Sterling's arguments regarding order Paragraph II is properly raised for the first time in a petition for reconsideration. See 16 C.F.R. § 3.55. Sterling had ample opportunity on appeal to contest the finding that its advertisements represented Bayer's superiority with respect to certain attributes. Indeed, the administrative law judge reached this finding (F. 329) and it is discussed in Sterling's Brief on Appeal (pp. 43, 85-86). Furthermore, Sterling took advantage of its opportunity on appeal to raise arguments regarding whether the 223 Study showed Bayer to be fresher, purer, more stable and

quicker to disintegrate. (In fact, in its appeal brief Sterling argued, in contrast to the position it now takes, that the results of the 223 Study should not be used to draw conclusions regarding any specific pharmaceutical attribute (p. 43).)

Paragraph III

Paragraph III of our order prohibits Sterling from making any therapeutic performance claims regarding a nonprescription internal analgesic unless it possesses a reasonable basis for that claim. Well-controlled clinical tests supporting a claim are deemed to be a reasonable basis. This provision is similar to Paragraph II of the order that we entered against Bristol-Myers and Sterling's objections are similar to those asserted by Bristol-Myers in its Petition for Reconsideration (Petition for Reconsideration pp. 2-6). For the reasons set forth below, we reject each of Sterling's arguments regarding Paragraph III and decline to modify it.

First, Sterling contends that Paragraph III is vague and imprecise, noting that these reasons were cited by the Third Circuit when it set aside a similar provision in the order that we entered against its competitor, American Home Products Corporation ("AHP"). However, as we explained in our response to Bristol-Myers' Petition for Reconsideration, there are important differences in the cases that are reflected in the challenged provisions. Paragraph III applies only to nonprescription analgesics and our opinion in this case contains an extensive discussion of analgesic testing. On the other hand, Paragraph II(D) in the AHP order applied to all drugs even though our opinion in that case contained no discussion of the criteria for testing any product other than analgesics. Moreover, Paragraph III sets forth a level of evidence (well-controlled clinical tests) that will constitute a reasonable basis. Paragraph II(D) contained no such standard.

Even more important, Paragraph II(D) was based only upon AHP's tension-relief claims for Anacin. On the other hand, as discussed in our opinion in this case, we found numerous instances in which Sterling had represented that Cope and Midol could relieve tension (Slip op. pp. 39-40). We also found that Sterling lacked a reasonable basis for these claims and for its comparative superiority claims regarding Bayer (Slip op. p. 38). Finally, we found that Sterling made numerous other nonestablishment claims which should be judged under a reasonable basis standard (*see e.g.*, slip op. pp. 16-19). Thus we found that Sterling lacked a reasonable basis for claims regarding three of its analgesics. Since it appears that Paragraph III would only apply to a total of five analgesics (slip op. p. 56), the order in this case is much narrower and more carefully tailored to the violation than the order provision rejected by the Third Circuit.

Sterling contends that the order does not give it adequate direction as to what constitutes a reasonable basis. It also contends that Commission advisory opinions are not an adequate means of curing this imprecision (Petition for Reconsideration pp. 3-4). We reject these arguments for the same reasons that we rejected identical arguments raised by Bristol-Myers.

Paragraph V

Paragraph V of our order prohibits Sterling from falsely representing that the analgesic ingredient in an aspirin-containing product is different from aspirin. This provision was based upon advertisements placed by Sterling regarding Midol. In its Petition for Reconsideration, Sterling contends that our interpretation of the Midol advertisements was inconsistent with our interpretation of advertisements disseminated by Bristol-Myers for Excedrin P.M. Sterling argues that its analgesic was different from aspirin (Petition for Reconsideration pp. 10-15).

Sterling misunderstands the portion of the Bristol-Myers decision that addressed the Excedrin P.M. advertisements. What we held in that decision was that Bristol-Myers did not represent that the sleep-inducing ingredient in Excedrin P.M. was *unique*. The complaint in that case did not allege that Bristol-Myers had represented that the sleep-inducing ingredient was different from another ingredient. In fact, advertisements for Excedrin P.M. do not contrast the sleep-inducing ingredient with the sleep-inducing ingredient in any other product.

The advertising for Midol is different. We did not find that the Midol advertisements represent that Midol's pain relieving ingredient is unique. Indeed, the Complaint contains no such allegation. Thus our interpretation of the Midol and Excedrin P.M. ads is consistent. However, we did find that advertisements for Midol represent that its pain-relieving ingredient is different from the pain-relieving ingredient in "ordinary pain relievers." Sterling contends that this finding is also inconsistent with our Bristol-Myers opinion. It argues that in *Bristol-Myers* we found that Bufferin and Excedrin ads falsely represented that the product did not contain aspirin by stressing the aspirin content of competing products and failing to disclose the aspirin content of Bufferin and Excedrin. Sterling seems to be arguing that since its Midol advertisements did not take the exact same approach as the Bristol-Myers advertisements the Commission could not find that the advertisements falsely differentiated the product's analgesic ingredient from aspirin.

We reject this argument. It is true that the approach taken in the Midol advertisements is not exactly the same as in those for Bufferin and Excedrin. Nonetheless, using a slightly different approach, Sterling created the impression that Midol's analgesic ingredient is other than aspirin. Since we discuss the Midol advertising in great detail in

the opnion on pages 45-48, there is no reason to repeat it here.

We reject Sterling's arguments regarding paragraph V for the reasons stated above and for the additional reason that the arguments are not timely. Petitioner would appear to argue that it had no opportunity to raise these arguments regarding paragraph V on appeal because it had not yet seen our decision in *Bristol-Myers*. However, although Sterling does mention the *Bristol-Myers* decision, in fact all of its arguments could have been raised in its appeal brief. Sterling chose to devote only one page of a 90 page appeal brief (p. 89) to the Midol advertising. It is not entitled to a second opportunity to raise those arguments now.

Conclusion

For each of the foregoing reasons, we deny Sterling Drug's Petition for Reconsideration in its entirety.

SEAL

ISSUED: October 14, 1983

EXCERPTS FROM INITIAL DECISION OF ADMINISTRATIVE LAW JUDGE HYUN

Dated January 30, 1981

314. It is found that a substantial number of respondent's Bayer advertisements in evidence did not make the representation alleged in Complaint Paragraph 10(A). They include, by way of examples, CX 73-78, 80-83, 105-108, 110-116, 162, 163.

315. For example, CX 78 is the storyboard of a 1973 television commercial (30 seconds) for Bayer Aspirin entitled "Woman's Place." The clear message of this commercial is that all aspirin is not alike and that Bayer's own test showed Bayer to be "the better quality aspirin." Throughout the commercial, every comparative (such as "better" or "superior") is qualified and clearly directed to "quality." There are no dangling superlatives or tag line closings which might confuse and mislead consumers to perceive this commercial as suggesting that Bayer is therapeutically superior to any other aspirin. It simply says Bayer is the "better quality aspirin" throughout the commercial. What it suggests is clearly that "you can count on Bayer," that Bayer will do what aspirin is supposed to do.

316. To cite another example, CX 75 (CX 75a) is a 1972 television commercial (30 seconds) for Bayer Aspirin entitled "Truisms." This was one of the two television commercials studied in the Zeisel Copy Tests (CX 520). The message is similar to that of CX 78 discussed above. Although the "quality" message is not as sharp as it is in CX 78. there is nothing in this commercial to suggest that it is talking about something other than Bayer's overall high "quality." It simply says "you can count on Bayer."

317. The Zeisel Copy Tests (CX 520) provides confirmatory evidence with respect to CX 75 (CX 75a). Table 1

of the Zeisel study shows that about 4% of the respondents (subject to a sampling error of ±7%, assuming the sample were a probability sample which it was not) played back superior "effectiveness" message for Bayer in response to open-ended questions 2 and 3 (CX 520H, P, Z37).

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1153. In 1971, the 223 Test was considered by a group which included such company scientific experts as Dr. Blackmore, Director of Clinical Research at Sterling's Research Laboratory; Dr. Rosenberg, Head of the Pharmacology Section of the Research Institute; Dr. Swarbrick, Head of the New Product Development Group and a former professor of Pharmaceutical Science (now Dean of the University of Southern California School of Pharmacy); Mr. Winig, Plant Manager at the Bayer Trenton plant and an expert in pharmaceutical and manufacturing standards in aspirin; Dr. Trout, Sterling Medical Director; and other medical personnel. A consensus was reached at those meetings that the 223 Test was valid and reliable and that it provided a basis for making a claim of superiority in pharmaceutical quality for Bayer Aspirin (Alberts, Tr. 9002-03; Winig, Tr. 13752; Trout, Tr. 16094).

1154. At the trial, respondent's expert witnesses, without exception, testified that because pharmaceutical quality is related to therapeutic efficacy, physicochemical pharmaceutical tests, such as CX 448, provide a reasonable basis for conclusions regarding comparative therapeutic performance of aspirin products.

1155. Dr. Horner, respondent's expert biostatistician, testified that in assessing the clinical significance of differences in various parameters between aspirin brands, it is necessary to consider the net effect of all differences, rather than to isolate a single parameter. In this opinion, a critical issue is the assessment of overall pharmaceutical and therapeutic superiority, as opposed to making a series of

independent decisions based on individual parameters (Horner, Tr. 10835).

1156. Dr. Feinstein testified that he reviewed the material in the "223 Test" (Feinstein, Tr. 16374). He described the study as containing the kind of evidence that he would resort to in making a decision as to which of the products would be better therapeutically (Feinstein, Tr. 16374, 16379).

1157. Dr. Rhodes, an expert in pharmaceutics, testified that, in his opinion, CX 448 is a valid pharmaceutical study, which demonstrates that when Bayer Aspirin was compared with a large number of other aspirin products available on the United States market, Bayer Aspirin was of better quality than those produced by its competitors. In his view, the 223 Test provides a reasonable scientific basis for the conclusion that Bayer Aspirin and Bayer Children's Aspirin have been tested against other brands of aspirin and found to be qualitatively superior to other brands. It would also be reasonable to draw a therapeutic conclusion based upon the therapeutic importance of the parameters measured in this study. In his opinion, a reasonable drug company in the late 1960's and early 1970's would have acted reasonably in selecting the parameters measured in the study in attempting to determine the pharmaceutical and therapeutic superiority of its aspirin over competitive brands of aspirin (Rhodes, Tr. 11425-26, 11434-43).

1158. It was the judgment of Dr. Banker, an expert in pharmaceutics, that the 223 Test was a comprehensive test which evaluated meaningful parameters of different brands of aspirin tablets. In Dr. Banker's view, the methodology is valid, and clearly established that Bayer was the most nearly optimized brand of aspirin tablets, and was pharmaceutically and therapeutically superior to the other brands evaluated. In his opinion, a reasonable drug company would have a right to rely on a study such as the 223 Test in

making superiority claims for its aspirin and a reasonable hospital pharmacist or clinician would be justified in relying on such a study in selecting Bayer Aspirin over other brands of aspirin tablets for treatment of patients (Banker, Tr. 12779-81; Danhof, Tr. 16946-67).

1159. Dr. Fields testified that the 223 Test was of value in selecting an aspirin brand to be used in the NIH Stroke Study because of the relationship between such characteristics and the therapeutic performance or side effects of an aspirin tablet. In the absence of controlled clinical studies, the 223 Test was considered to have a bearing upon determining which aspirin brand would produce the least variability, the most likelihood of bioavailability, and the least side effects. Among the physical and chemical characteristics considered were disintegration, amount of impurities, including free salicylic acid, and the stability of the tablet. According to Dr. Fields, the expert pharmacologists relied upon the 223 Test and other information in selecting Bayer Aspirin for use in the NIH Stroke Study (Fields, Tr. 16585-86, 16598-600, 16566, 16744-45).

1160. Dr. Scoville, a former FDA official, also testified that the 30 physical and chemical characteristics studied in the 223 Test were included in the type of material that is reviewed by the FDA, together with appropriate clinical data, in reaching judgments as to the safety and efficacy of a drug product and in determining whether to approve a drug for marketing or to seize or recall a drug product from the marketplace (Scoville, Tr. 14448-49).

1161. Dr. Falliers, an expert in allergy, testified that to the extent that the 223 Test demonstrated that Bayer Aspirin is pharmaceutically superior in the characteristics tested, it provided a reasonable basis to conclude that Bayer Aspirin is therapeutically superior (Falliers, Tr. 13320-21, 13326).

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